CREATIVE MEDICAL

Patient Monitor

PC-5000

User Manual

This Manual is written and compiled in accordance with the IEC 60601-1（Medical electrical equipment Part1: General requirements for safety）,and MDD 93/42/EEC. It complies with both international and enterprise standards and is also approved by State Technological Supervision Bureau. The Manual is written for the current PC-5000 Patient Monitor.

The Manual describes, in accordance with the PC-5000 Patient Monitor's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

The Manual is published in English and we have the ultimate right to explain the Manual. No part of this manual may be photocopied, reproduced or translated into another language without the prior written consent. We reserve the right to improve and amend it at any time without prior notice. Amendments will however be published in a new edition of this manual.

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Marks in the Manual:

- **Warnings: must be followed to avoid endangering the operator and the patient.**
- **Notes: contains some important information and tips about operations and application.**
- **Attentions: must be followed to avoid causing damage to the monitor.**

3502-2300001

Instructions to User

Dear Users,

Thank you very much for purchasing our product. Please read the following pages very carefully before using this equipment.

Read these instructions carefully before using this monitor. These instructions describe the operating procedures to be followed strictly. Failure to follow these instructions can cause monitoring abnormity, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormity, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

- **WARNING-PACEMAKER PATIENTS – Hreat rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate meter ALARMS. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.**
- **Monitoring a single person at a time.**
- **The monitor is defibrillator proof. Verify that the accessories can function safely and normally and the monitor is grounded properly before conducting defibrillation.**
- **Disconnect the monitor and sensors before MRI scanning. Use during MRI could cause burns or adversely affect the MRI image or the monitor's accuracy.**
- **If you have any doubt to the grounding layout and its performance, you must use the built-in battery to power the monitor.**
- **All combinations of equipment must be in compliance with standard of IEC 60601-1-1 medical and electric system requirements.**
- **Check SpO_2 probe application site periodically (every 30 minutes) to determine circulation, positioning and skin sensitivity.**
- **The SpO_2 measurement of this monitor may not work for all testees. If stable readings can not be obtained at any time, discontinue to use.**
- **Do not immerse the monitor or its accessories in liquid to clean.**
- **Do not use accessories other than those provided/recommended by the manufacturer.**
- **Each time the monitor is used, check the alarm limits to ensure that they are appropriate for the patient being monitored.**
- **The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.**
- **When taking the measure of a pediatric or neonate's (less than 10 years old) blood pressure, do NOT operate in the adult mode. The high inflation pressure may cause lesion or even body putrescence.**

- **The monitor is prohibited from applying to those who have severe hemorrhagic tendency or who are with sickle cell disease for they may develop partial bleeding when this monitor is used to take the blood pressure measurement.**
- **DO NOT take blood pressure measurement for a limb receiving ongoing transfusion or intubations or skin lesion area, otherwise, damage may be caused to the limb.**
- **Continuous use of SpO_2 sensor may result in discomfort or pain, especially for those with microcirculatory problem. It is recommended that the sensor should NOT be applied to the same place for over two hours, change the measuring site periodically if necessary.**
- **SpO_2 measuring position must be examined more carefully for some special patients. Do NOT install the SpO_2 sensor on the finger with edema or vulnerable tissue.**
- **To prevent the risk of the short circuit and to ensure the ECG signal quality, the equipment must be properly grounded.**
- **Although biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do NOT apply to those who have anaphylaxis.**
- **All the connecting cables and rubber tubes of the applied parts should be kept away from the patient' s cervix to prevent any possible suffocation of the patient.**
- **All the parts of the monitor should NOT be replaced at will. If necessary, please use the components provided by the manufacturer or those that are of the same model and standards as the accessories along with the monitor which are provided by the same factory, otherwise, negative effects concerning safety and biocompatibility etc. may be caused.**
- **DO NOT stare at the infrared light of SpO_2 sensor when switch it on, for the infrared may do harm to the eyes.**
- **If the monitor falls off accidentally, please do NOT operate it before its safety and technical indexes have been tested minutely and positive testing results obtained.**
- **It is recommended to take the blood pressure measurement manually. The automatic or continuous mode should be used at the presence of a doctor/nurse.**
- **Reuse, disassembly, cleaning, disinfecting or sterilizing the single patient use CO_2 cannula kits and on-airway adapters may compromise functionality and system performance leading to a user or patient hazard. Performance is not guaranteed if an item labeled as single patient use is reused.**
- **Electrical Shock Hazard: Always disconnect the CO_2 Sensor before cleaning. Do NOT use if it appears to have been damaged. Refer servicing to qualified service personnel.**
- **Electrical Shock Hazard; No user serviceable parts inside the CO_2 Sensor.**
- **After the life cycle of the Sidestream CO_2 Sensor and its accessories has been met, disposal should be accomplished following national and/or local requirements.**
- **Please peruse the relative content about the clinical restrictions and contraindication.**
- **When disposing of the monitor and its accessories, the local law should be followed.**

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Chapter 1 Overview

1.1 Features

This monitoring system may be used to monitor patient's 6 physiological parameters: ECG, respiratory rate, body temperature, non-invasive blood pressure (NIBP), pulse oxygen saturation (SpO_2) and pulse rate.

- ✧ 10.4″ high-resolution color LCD to display patient's ECG waveform, respiratory waveform and SpO_2 cubage waveform;
- ✧ Abundant and friendly display interface, multifold ECG display screen:

  Main monitoring screen: displays the information of all the waveforms and parameters visually.

  Observing screen: dispalys heart rate value and SpO_2 value in big fonts and an ECG waveform and a SpO_2 cubage waveform will be displayed at the same time.
- ✧ Automatic analysis of 20 arrhythmia waveforms and ARR, waveform freezing function and automatic ST segment measurement and manual analysis;
- ✧ Up to 480 hours statistic data of HR, TEMP, SpO_2, RESP and NIBP trends;
- ✧ 100 groups of arrhythmia cases' data and the corresponding ECG, TEMP, SpO_2, RESP and pulse value of each case;
- ✧ Storage and recall of a list of 800 groups of NIBP measurement data, as well as heart rate, body temperature, respiratory rate and SpO_2/pulse rate when the measure of blood pressure is taken;
- ✧ Nonvolatile 6hours of ECG data storage and recall;
- ✧ High precision NIBP measuring module, good repeat capability;
- ✧ Software and hardware-dual excess air pressure protection function;
- ✧ Special SpO_2 measuring device, which ensures the accuracy of SpO_2 and pulse rate measures;
- ✧ Unique file management, which enables recording, modifying, deleting and saving operation of patient's information.
- ✧ Precise alarm system, different alarm events adopt different alarm degrees; 3 degrees visual and audible alarm function;
- ✧ Flexible high and low alarm limits setting function;
- ✧ Resistance against defibrillator and electrosurgical knife interference; Cardiac pacemaker restraining function enables the monitor to be used along with cardiac pacemaker;
- ✧ Blood pressure may be measured in the mode of "adult/infant/neonate", which may be selected via the menu to better suit the adult or infant or neonate patient;
- ✧ Built-in printer (optional) to output waveforms and text;
- ✧ Networking with the central station as a part of the central network;
- ✧ Easy to color-code and change the color of the font, background and waveforms if needed;
- ✧ Battery power indicator, which enables real-time battery power detection and displays the battery power.

1.2 Product Name and Model

Name: Patient Monitor

Model: PC-5000

1.3 Applications and Scope

This Patient Monitor is a multi-functional instrument designed for monitoring the vital physiological signs of adult and pediatric patients. With the functions of real-time recording and displaying parameters, such as ECG, heart rate, non-invasive blood pressure, functional oxygen saturation, end-tidal CO_2 concentration, respiration rate, body temperature, and so on, it allows comprehensive analysis of patient's physiological conditions.

This instrument is applicable for use in hospitals and clinical institutions. The operation should be performed by qualified professionals only.

1.4 Requirements of Operating Environment and Installation

1. This device should be situated in a place protected against direct sunlight, so as to prevent overheating inside the equipment.
2. Do not use this device in an environment with toxic or inflammable gas.
3. This device should be fixed on a stand or flat platforms, so as to prevent possible shock.
4. Do not use this apparatus in combination with any equipment other than those expressly permitted in this instruction.
5. When using this device with electrosurgical equipment, the user (doctor or nurse) should pay attention to the safety of patient.
6. Make sure that the equipotential grounding terminal is grounded correctly.
7. Do not use mobile phone nearby, so as to avoid strong radiant field interference.

1.5 Normal Working Environment

1. Ambient temperature range: 5℃ ~40℃
2. Relative humidity: 30%~80%
3. Atmospheric pressure: 70.0kPa ~106.0kPa
4. Power supply: AC 100~240V
5. Power frequency: 50/60Hz

1.6 Impact on Environment and Resources

Low

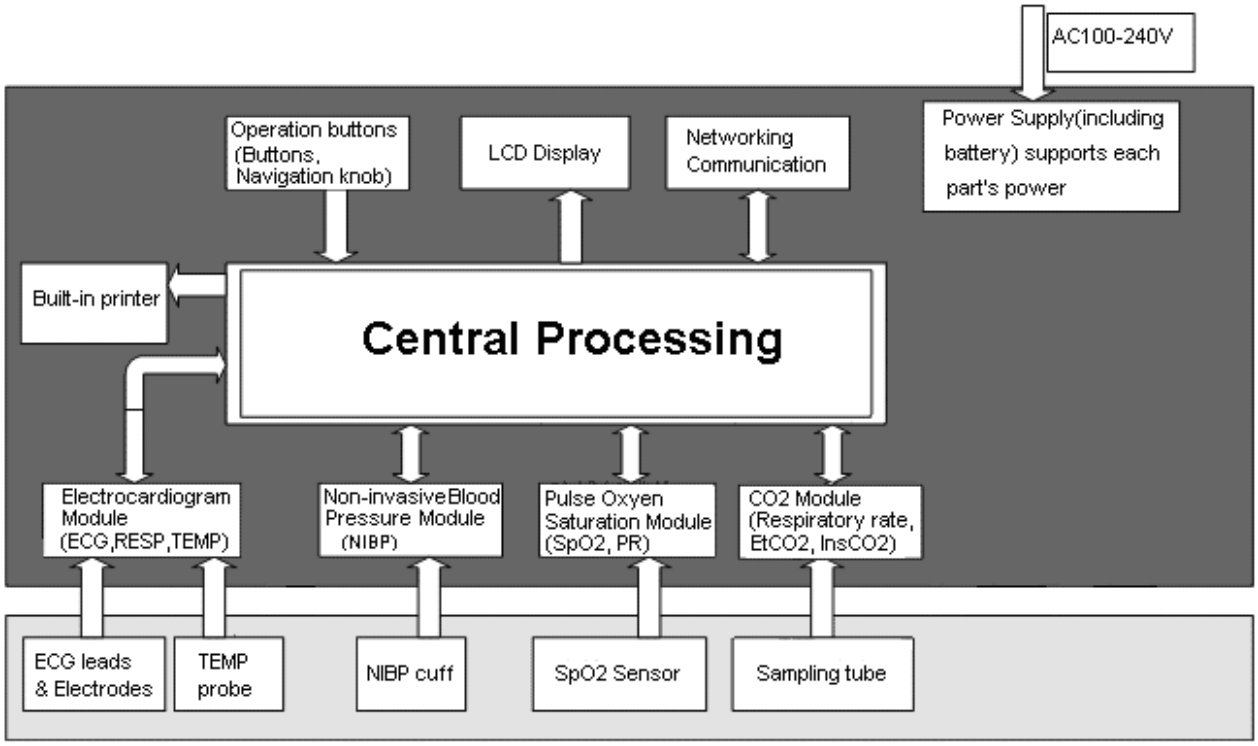
1.7 Safety

a) This device conforms to IEC60601-1, electric safety classification: Class I, with Type BF and CF applied parts.
b) This device can resist against the discharge of defibrillator and the interference of electro-surgical unit.
c) This device can monitor the patients with pace-maker.
d) DO NOT use this device while the patient is under MRI scanning.

Chapter 2 Working Theories of the Main Unit

2.1 Overall Structure and Working Theories

The overall structure of this monitor is shown as Fig.2.1.



PC-5000 Patient Monitor is a product of modular design. It performs its measurement of the physiological parameter through different modules. There are five functional modules for the monitor: ECG module, NIBP module, SpO_2 module, CO_2 module (optional) and Central Processing Unit (CPU) module.

1. ECG module collects heart rate, respiration waveforms through the ECG leads and electrodes. It also collects temperature data from the temperature transducer.
2. SpO_2 module collects data for pulse rate, pulse oxygen saturation (SpO_2) and SpO_2 volume waveform via the SpO_2 probe.
3. NIBP module collects blood pressure data, including the diastolic, systolic and mean arterial pressure through the NIBP cuff. The cuffs are sized for adult, infant and neonate respectively, NIBP measure has three modes: adult and infant and neonate.
4. The CO_2 module collects the date of respiration rate, $EtCO_2$, $InsCO_2$ through the sampling tube.
5. CPU module consists of main board, multi-function board, and the keyboard. The multi-function board performs the data communication between the main board, ECG module, SpO_2 module NIBP module, and CO_2 module.

2.2 Composition

1. The monitor consists of the main unit and the corresponding functional components (ECG leads & electrodes, non-invasive blood pressure cuff, SpO_2 probe, temperature transducer and side-stream CO_2).
2. The monitor has 4 measurement channels: ECG and respiration channel, NIBP channel, SpO_2 and pulse channel and temperature channel.
3. The monitor has two output channels: networking communication port and printer.
4. Basic parameters include: heart rate, respiration rate, NIBP, SpO_2, pulse rate and temperature.

Chapter 3 Installation and Connection

3.1 Panel Introduction

3.1.1 Front Panel

Figure 3.1 PC-5000 Front Panel

The patient monitor front panel is shown above:

1 Power switch

Press it to turn on the monitor, press it again to turn off the monitor.

2 AC power indicator

When AC indicator is on, it means this device is using mains power supply.

3 : DC build-in battery indicator

When DC indicator is on, it means the battery is being used; when both of AC indicator and DC indicator light are on, it means that this device is using mains power supply and the battery is being recharged.

4 LEAD switch

Click it to shift the ECG monitoring circulatory among aV,RI,aVL, aVF, V and GND.

5 ALARM

Press this key to setup the alarm function.

In monitoring screen, press this key to set the alarm silence time. The time shows on the upper left corner. The system starts count-down after the alarm silent time is set and will activate the alarm when the count-down ends. The alarm silence time has 4 settings: 2 min, 5 min, 10 min and 20 min, or in alarm.

DO NOT silence the audible alarm or decrease its volume if patient safety could be compromised.

6 Navigation Knob

By rotating the navigation knob, the operator can choose the function and parameters. By pushing down and releasing the knob, the operator can switch screen, confirm operations.

The majority of the operations of the monitor are performed by using navigation knob.

7 FREEZE

Press this key to freeze ECG waveform, or ECG, SpO_2 and RESP waveform based on the freezing settings in the system. It also enters the ST segment manual analysis screen.

8 NIBP

Press this key to start NIBP measurement. Press it again to stop the measurement.

9 PRINT

Press this key to print different waveforms on different screens.

In the main screen, archive/file management screen, color setting screen, it prints the ECG waveform, SpO_2 waveform or respiration waveform.

In the NIBP data-listing screen, it prints the NIBP data list.

In the SpO_2 data- listing screen, it prints the SpO_2 data list.

In the Trend screen, it prints the system trend graph.

In the System menu, it prints the system parameter settings.

In the Recall screen, it prints the Recalled data list or prints current lead's ECG waveform and Recalled waveform.

In ARR monitoring screen, it prints the ARR data list or current lead's ECG and the arrhythmia data.

10 DISP (Display)

Press this key to switch between initial monitoring screen and Observe Screen, and press it again to return to the main screen from other screens.

11 Alarm indicator

Indicator Color	Alarm Level	Alarm Event
Red flashing	High priority alarm	Exceeding the limits, pulse stop or suffocation
Yellow flashing	Middle priority alarm	Leads and probe off, VE RONT and SVE RONT
Yellow light	Low priority alarm	Other arrhythmia phenomenon
Green light	Normal	

3.1.2 Left and Right Side Panel

Figure 3.2 Left panel

Figure 3.3 Right panel

The built-in printer is on the left panel as shown in Figure 3.2.

The right panel of the monitor hosts the patient cable and probe jacks, as shown in Figure 3.3.

1. **NIBP -** NIBP hose connector
2. **SpO_2 -** SpO_2 sensor connector
3. **TEMP** - Temperature probe connector
4. **ECG/RESP -** ECG cable connector
5. **CO_2 :** Cable connector of CO_2 sensor module
6. -Battery cover, remove the cover to install or change rechargeable battery. Factory default: two rechargeable batteries (12V 2.3Ah); battery specification: FB 12V 2300mAh.

   "TO AVOID BATTERY DAMAGE, ALWAYS REMOVE BATTERY(S) BEFORE SHIPPING OR STORAGE"

With Type BF applied parts

With Type CF applied part and applicable during the defibrillator is used.

Caution! Please read the manual for details.

3.1.3 Back Panel

Figure 3.4 Back panel

The back panel of the monitor includes the following:

1. **MONITOR:** External monitor port
2. **NET:** Communication port which is used to network with central monitoring system
3. **:** Equipotential grounding port
4. **FUSE 2×T3.15A:** Fuse holder; fuse specification: T3.15AL/250V Φ5×20mm
5. **AC 100V~240V:** Power supply socket
6. **S/N:** Serial Number
7. **Nameplate**

CE	CE mark
SN	Serial number
	Date of manufacture
EC REP	Authorised representative in the European community
	Manufacturer (including address and date)
	Disposal of this device according to WEEE regulations

3.2 Installation

3.2.1 Opening the Box and Check

1. Open the packaging, take out the monitor accessories from the box carefully and place it in a safe, stable and easy to watch position.
2. Open the users' manual to sort the accessories according to the packing list.
   - ◆ Inspect the accessories for any mechanical damages
   - ◆ Check all the exposed leads and inserted accessories

Please contact the local dealer or our company in case of any problems. We are to offer you the best solution for your satisfaction.

3.2.2 Connecting the AC Power Cable

1. When powered by AC mains power supply:

- ◆ Make sure that the AC power supply is 100-240VAC, 50/60Hz.
- ◆ Use the power cable prepared by the manufacturer. Insert one end of it to the power port of the monitor and the other end to the grounded three-phase power jack.
- ◆ To eliminate potential differences, the monitor has a separate connection to the equipotential grounding system. Connect one end of the provided ground cable to equipotential grounding port on the rear panel, and connect the other end to one point of the equipotential grounding system.

Caution: ensure that the monitor is grounded correctly.

🔔 If the mains power supply has been interrupted when power switch remains in the "on" position and is restored after a period of time (longer than 30 seconds), the monitor will run by the last settings when restarting the monitor.

2. When powered by built-in battery

- ◆ Caution: it's better to recharge the battery after it is used up, and the charging time should be 13~15 hours long.

🔔 The provided battery of the monitor must be recharged after transportation or storage. So if the monitor is switched on without being connected to the AC power socket, it may not work properly due to insufficient power supply.

3.2.3 Starting the Monitor

The system performs self-detection and enters initial display after the monitor is switched on, and the orange alarm indicator blinks to inform that the user can begin operating it.

- ◆ Check all the applicable functions to make sure that the monitor works normally.
- ◆ If the built-in battery is applied please recharge it after using the monitor to ensure sufficient power storage. It will take at least 8 hours to charge battery from depletion to 90% charge

💣 Do not use the monitor to monitor the patient if there are indications of damage or reminders of error. Please contact the local dealer or our company.

🔔 Restart the monitor 1 minute later after it is switched off.

3.3 Connection

3.3.1 ECG Connection

ECG measurement is to collect the ECG signals via the ECG electrodes. Electrode connects the patient and the lead. The lead connects the monitor. The locations of the electrodes are very important for obtaining accurate ECG signals.

1. Connect the cable to the right-panel connector marked with the ECG icon.
2. Select electrodes to be used. Use only one type of electrode on the same patient to avoid variations in electrical resistance. For ECG monitoring, it is strongly recommended to use silver/silver chloride electrodes. When dissimilar metals are used for different electrodes, the electrodes may be subject to large offset potentials due to polarization. Using dissimilar metals may also increase recovery time after defibrillation.
3. Prepare the electrode sites according to the electrode manufacturer's instructions.
4. Skin clean

- Clean and dry-abrade skin to ensure low sensor impedance. Mild soap and Water is recommended as a skin cleanser.

  Note: Alcohol is not recommended as a skin cleanser; for it leaves a film layer that may cause high sensor impedance. If alcohol is used, ensure 30-second dry time.

- Dry-abrading the skin gently with a dry wash cloth, gauze, because skin preparation is helpful to remove the non-conductive skin layer.

The symbol indicates that the cable and accessories are designed to have special protection against electric shocks and be defibrillator-proof.

The locations of the electrode are in the following Figure:

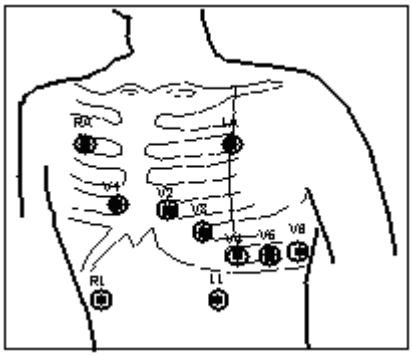


Figure 3.5 Locations of Electrodes

Note: If skin rash or other unusual symptoms develop, remove electrodes from patient.

5. After starting the monitor, if the electrodes become loose or disconnected during monitoring, the system will display "*LEAD OFF*" on the screen to alarm the operator.

🔔 **It might not display ECG wave with 3 leads. The 5 leads should be used to have ECG wave.**

6. The ECG leads and their corresponding locations are as follows:

Symbol		Position
RA		The intersection between the centerline of the right clavicle and Rib 2
LA		The intersection between the centerline of the left clavicle and Rib 2
LL		Left part of the upper abdomen
RL		Right part of the upper abdomen
C (V) Chest electrode	C1(V1)	The electrodes are placed in different places, the different lead forms will display.
	C2(V2)	
	C3 (V3)	
	C4 (V4)	
	C5 (V5)	
	C6 (V6)	

Safety Instructions for ECG Monitoring

- PC-5000 Patient Monitor can only be equipped with ECG leads provided by our company; using ECG leads supplied by other companies may cause improper performance or poor protection while using defibrillator.
- Electric parts of electrodes, leads and cable are forbidden to contact any other conductive parts (including ground).
- PC-5000 Patient Monitor can resist against defibrillator and electrosurgical unit. Readings may be inaccurate for a short time after or during using defibrillator or electrosurgical unit.
- Transient caused by cable circuitry blocks while monitoring may be similar to the real heartbeat waveform, as a result resistance heart rate alarm rings. If the electrodes and cable are located in proper places according to this manual's instructions and the instructions for using electrode, the chance of this transient occurrence will be decreased.
- To the patient with pacemaker, because this device has been designed to provide resistance to pacemaker signal interference, generally the pacemaker pulse is not counted in heart rate measurement and calculation, but when the cycle time of pacemaker pulse is over 2ms, it may be counted. In order to reduce this possibility, observe the ECG waveforms on the screen carefully and do NOT rely entirely on the heart rate display and alarm system of this monitor when monitoring this kind of patients. Keep pacemaker patient under close surveillance.
- The improper connection with electrosurgical unit may not only cause burns, but also damage the monitor or arouse deviations of measurement. You can take some steps to avoid this situation, such as do NOT use small ECG electrodes, choosing the position which is far away from the estimated Hertzian waves route, using larger electrosurgical return electrodes and connecting them with the patient properly.
- No predictable hazard will be caused by the summation of leakage currents when several item of monitor are interconnected.
- ECG leads may be damaged while using defibrillator. If the leads are used again, please do the functional check first.
- When the monitor is inoperable due to overload of ECG module or saturation of any part of the amplifier, it will prompt "Lead off" to remind operator.

3.3.2 Blood Pressure Cuff Connection

1. Connect the cable to the right-panel connector marked with the NIBP icon.
2. Unveil the cuff and wrap it around patient's upper arm.

Requirements of the cuff:

1) Appropriate cuff should be selected according to the age of the subject. Its width should be 2/3 of the length of the upper arm. The cuff inflation part should be long enough to permit wrapping 50-80% of the limb concerned. See the table below for the dimensions:

Note: The size of the cuff selected should suit the subjects while measuring.

Cuff Model	Arm Circumference	Cuff Width
Small-sized Infant Cuff	6cm～11cm	4.5cm
Middle-sized Infant Cuff	10cm～19cm	8cm
Large-sized Infant Cuff	18cm～26cm	10.6cm
Adult Cuff	25cm～35cm	14cm

2) When putting on the cuff, unveil and wrap it around the upper arm evenly to appropriate tightness.
3) Remember to empty the residual air in the cuff before the measurement is commenced.
4) Locate the cuff in such a way that the "φ" mark is at a location where the clearest pulsation of brachial artery is observed.
5) The cuff should be tightened to a degree where insertion of one finger is allowed.
6) The lower end of the cuff should be 2cm above the elbow joint.

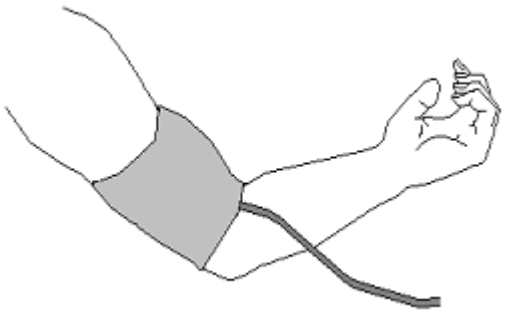


Figure 3.6 Cuff Position

When unplugging the cuff, hold the head of the connector and pull it out.

- **Pressure Accuracy Verification**

Pressure Accuracy Verification is a function to inspect the accuracy of pressure measurement by the NIBP module inside the device. Technician or equipment manager should do pressure accuracy verification every half year or year in order to check if the pressure measurement still conforms to the requirement of product performance. If the deviation is beyond the declared specification, it is permitted to return it to factory for repair or calibration.

Before verification, please connect the monitor to a standard pressure meter as the reference equipment like a mercury pressure meter

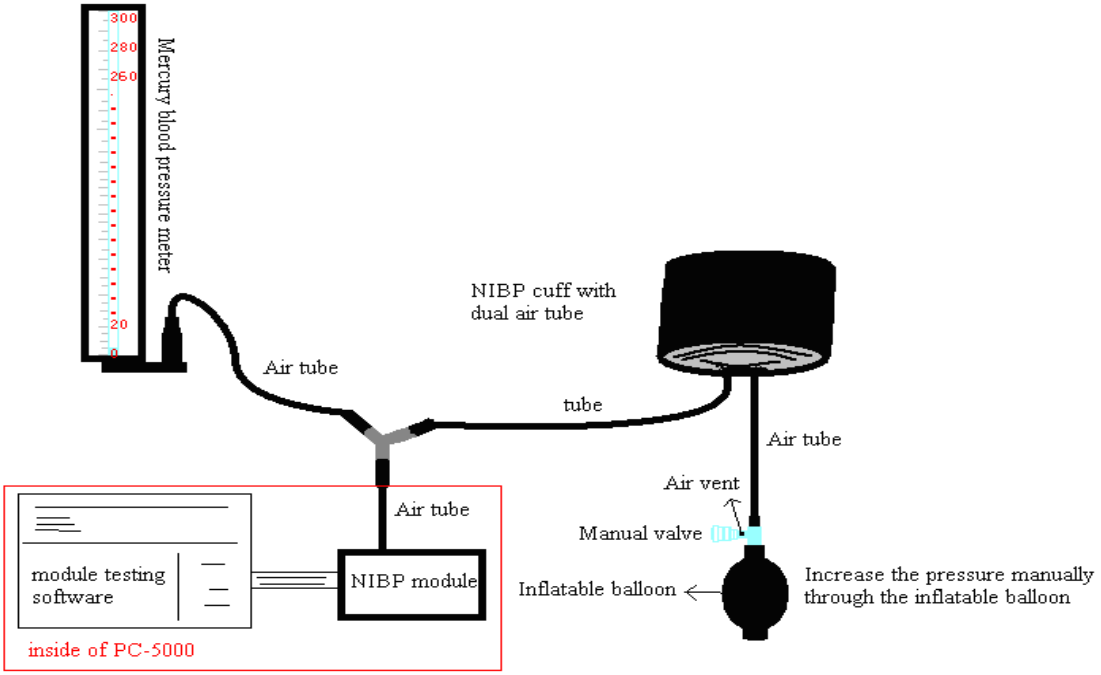


Figure 3.7 Connection of Pressure calibration fixture

Mode 1: The inflation can be activated by Monitor so the pressure will increase automatically until it exceeds the limit value specified in table A. This pressure limit value depends on the patient type selection as shown in table A:

Adult	240mmHg
Child	200mmHg
Neonate	120mmHg

Table A

During the inflation, the Monitor will close the deflating valve, and the pressure value will be shown during the process. If there is no manual deflation operation, the pressure will persist until deflation by manual operation, so it is necessary to use a manual valve for doing adequate deflation in several steps to verify the pressure accuracy in the full scale of measurement range.

Mode 2: No automatic inflation by Monitor during the pressure accuracy verification.

Increase the pressure manually by the pumping balloon, and the verification can be done by applying different pressure value manually. If the increased pressure exceeds the given limit as shown in table B, the Monitor will deflate automatically because of over-pressure protection.

Adult	300mmHg
Child	240mmHg
Neonate	140mmHg

Table B

- **After the verification, do press the button again to return to normal working mode, then continue other operation, or the NIBP key will be invalid.**
- **Pressure accuracy verification must be operated by technician or equipment manager. Doctor or nurse is not allowed to do the verification, it is very dangerous especially when the pressure cuff is still on patients.**

➢ **Air Leakage Check**

In order to avoid significant error of blood pressure measurement or even no measurement result caused by air

leakage in the pneumatic system including the cuff during measuring, it is recommended to check if there is leak in the pneumatic system as well.

- **Please remove the cuff from patient while performing the leakage check.**

Safety Instructions for NIBP Monitoring

- When taking the measure of an infant's (less than 10 years old) blood pressure, do NOT operate in the adult mode. The high inflation pressure may cause lesion or even body putrescence.
- It is recommended to take the blood pressure measurement manually. Automatic or continuous measurement should be used at the presence of a doctor/nurse.
- NIBP monitoring is prohibited to those who have severe hemorrhagic tendency or with sickle cell disease, or partial bleeding will appear.
- Do NOT bind NIBP cuff on limbs with transfusion tube or intubations or skin lesion area, otherwise, damages may be caused to the limbs.
- Pay attention to the color and sensitivity of the limb when measuring NIBP; make sure the blood circulation is not blocked. If blocked, the limb will discolor, please stop measuring or remove the cuff to other positions. Doctor should examine this timely.
- The time of the automatic pattern noninvasive blood pressure measurement pulls too long, then the body connected with the cuff possibly have the purpura, lack the blood and the neuralgia. When guarding patient, it is a must to inspect the luster, warmth and sensitivity of the body far-end frequently. Once any exception is observed, please stop the measurement immediately.
- The subject should lie on the back so that the cuff and the heart are in a horizontal position and the most accurate measure will be taken. Other postures may lead to inaccurate measurement.
- Do not speak or move before or during the measurement. Take care to avoid that the cuff will be hit or touched by other objects.
- The measures should be taken at appropriate intervals. Continuous measurement at too short intervals may lead to pressed arm, reduced blood flow, lower blood pressure and inaccurate measurement of blood pressure. It is recommended the measure be taken at intervals of more than two minutes.
- When an adult subject is monitored, the machine may fail in giving the blood pressure measure if the infant mode is selected.
- Prior to use of the cuff, empty the cuff until there is no residual air inside it to ensure accurate measurement.
- Do NOT twist the cuff tube or put heavy things on it.
- When unplugging the cuff, hold the head of the connector and pull it out.

The symbol indicates that the cable and accessories are designed to have special protection against electric shocks and be defibrillator-proof.

3.3.3 To connect the SpO_2

SpO_2 probe is very delicate equipment. Please follow the steps and procedures in operating it. Failure to operate it correctly can cause damage to the SpO_2 probe.

Operation procedure:

1. Connect the SpO_2 probe to the right panel's jack labeled "SpO_2". **When unplugging the probe, be sure to hold the head of the connector and pull it out.**

2. Insert one finger into the probe (index finger, middle finger or ring finger with proper nail length) according to the finger mark on the probe, shown as below.

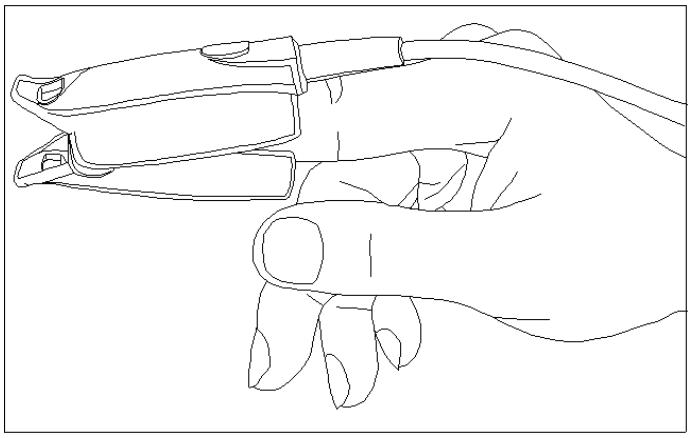


Figure 3.8 Demonstration of SpO_2 Probe

When selecting a sensor, do consider the patient's category, adequacy of perfusion, availability of probe site and anticipated monitoring duration. Use only SpO_2 probes provided by our company with this monitor. Read the following table for SpO_2 probe information. Refer to Chapter 11.6 for the detailed instructions of each SpO_2 probe.

SpO_2 Probe	Patient Category
SpO_2 Finger clip Sensor (reusable)	**Pediatric**
SpO_2 Finger rubber Sensor(reusable)	**Adult**
SpO_2 Finger clip Sensor(reusable)	**Adult**

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of a SpO_2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

Failure to take this action in high ambient light conditions may result in inaccurate measurements.

If patient movement presents a problem, verify that the sensor is properly and securely applied; move the sensor to a less active site; use an adhesive sensor that tolerates some patient motion; or use a new sensor with fresh adhesive backing.

For reusable sensors, follow the sensor directions for use for cleaning and reuse. For single-patient use sensors, use a new sensor for each patient. Do not sterilize any sensor by irradiation, steam, or ethylene oxide.

Safety Introductions for SpO_2 Monitoring

- Continuous use of fingertip SpO_2 sensor may result in discomfort or pain, especially for those patients with microcirculatory problem. It is recommended that the sensor should NOT be applied to the same finger for over two hours, change the measuring site periodically if necessary.
- SpO_2 measuring position must be examined more carefully for some special patient. Do NOT install the SpO_2 sensor on the finger with edema or fragile tissue.
- Do NOT put the SpO_2 sensor and pressure cuff on the same limb, otherwise the NIBP measuring will affect SpO_2 measuring and cause the alarm error.

If sterile packaging of SpO_2 sensor is damaged, do not use it any more.

- Check the SpO_2 sensor and cable before use. Do NOT use the damaged SpO_2 sensor.
- When the temperature of SpO_2 sensor is abnormal, do not use it any more.
- Please do not allow the cable to be twisted or bended.
- Please do not use nail polisher or other cosmetic product on the nail.
- The fingernail should be of normal length.
- The SpO_2 sensor can not be immerged into water, liquor or cleanser completely, because the sensor has no capability of waterproofness.

3.3.4 TEMP Transducer Connection

Patient Monitor has two TEMP transducers to measure different body temperature.

Connecting methods:

1. Attach the transducers to the patient firmly;
2. Connect them to “TEMP” on the right panel.

Note: When unplugging the probe, be sure to hold the head of the connector and pull it out.

3.3.5 Battery Installation

1. Make sure that monitor doesn’t connect to mains power supply and stays in switch-off status.
2. Open the battery cover, insert the battery into any slot of battery compartment, and pay attention to the instruction of polarity direction in the compartment. Do not reverse the battery.
3. Move baffle plate with hand to fasten the battery.
4. Remove the battery cover. (you can insert one more storage battery to prolong using time according to your need.)

- Please take out the battery from battery compartment, if it won’t be used for a long time.

3.3.6 Loading Printing Paper

This description is for loading paper for the built-in printer.

Operation procedures:

1. Press both “OPEN” notches with force on printer shield with two thumbs to open it.
2. Move the tab of rubber roller lock at the left 90°upwards to unlock it.
3. Cut one end of the paper into triangle, and load the paper from the underside of the rubber roller.
4. Turn the roller clockwise to get the paper rolled, and put the paper roll into the compartment.
5. Pull the paper out of paper slot on the shield.
6. Move the tab of the rubber roller lock 90° downwards to lock it.
7. Put the shield back in position and secure it.

P8 printer may be used due to the different configuration.

P8 printer operation instruction:

Power indicator: green light shows the power is on, while the monitor is out of power, the green light is off.

Error indicator: red light is constant which shows the printer is out of paper, or the printing paper does not install well. When the printer installs normally, the red light is off.

Figure 3.9 P8 Printer

Loading printing paper:

Step 1: press and hold down the cartridge button to open the paper cartridge;

Step 2: Install the paper to the printer properly, pull the paper out of the printer for 2 cm, as shown in figure 3.10.

Step 3: Close the printer cover along the direction of arrow, as shown in figure 3.10.

Figure 3.10 Printing Paper

Chapter 4 Monitoring Screen

4.1 Main Screen

4.1.1 Date and Time Setup

Instead of entering into monitoring screen, it shows the date and time setting screen immediately after the monitor is started, shown as Figure 4.1:

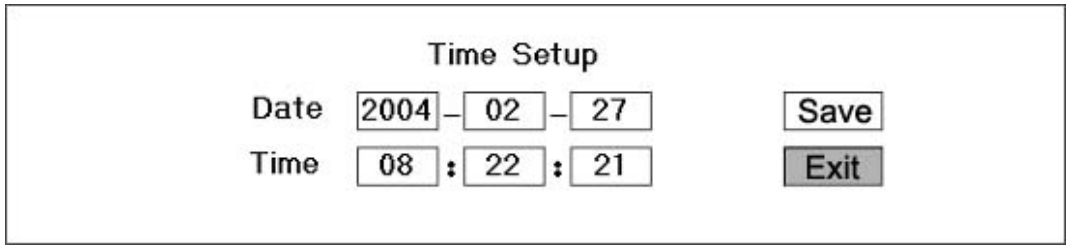


Figure 4.1 Date and Time Setup

The system will stay on this screen for 10 seconds. If you do not rotate the navigation knob within this period, the screen will enter into the Main Screen.

Follow the steps below to set date and time.

Step 1: Rotate Navigation Knob, move the gray cursor to “Edit”.

Step 2: Press the knob, and then gray cursor stays on the Year of the date. Press the knob again and the gray cursor becomes highlighted. Rotate the knob left or right to increase or decrease the year value.

Step 3: When the Year is set, press the knob to move the gray cursor to the Month of the date.

Step 4: Repeat Step 2 and Step3 to adjust the Year, Month, Date, Hour and Minute.

Step 5: If you have finished adjusting the date and time, press the knob and rotate the knob to move the cursor to “Save”, press it to save the settings. Then move the cursor to “Exit”, press it to exit the date and time setting screen, meanwhile enter into the main screen shown in Figure 4.2.

The system is initialized and enters into Main Screen where monitoring and system operation are performed. (shown in Figure 4.2)

4.1.2 Screen Description

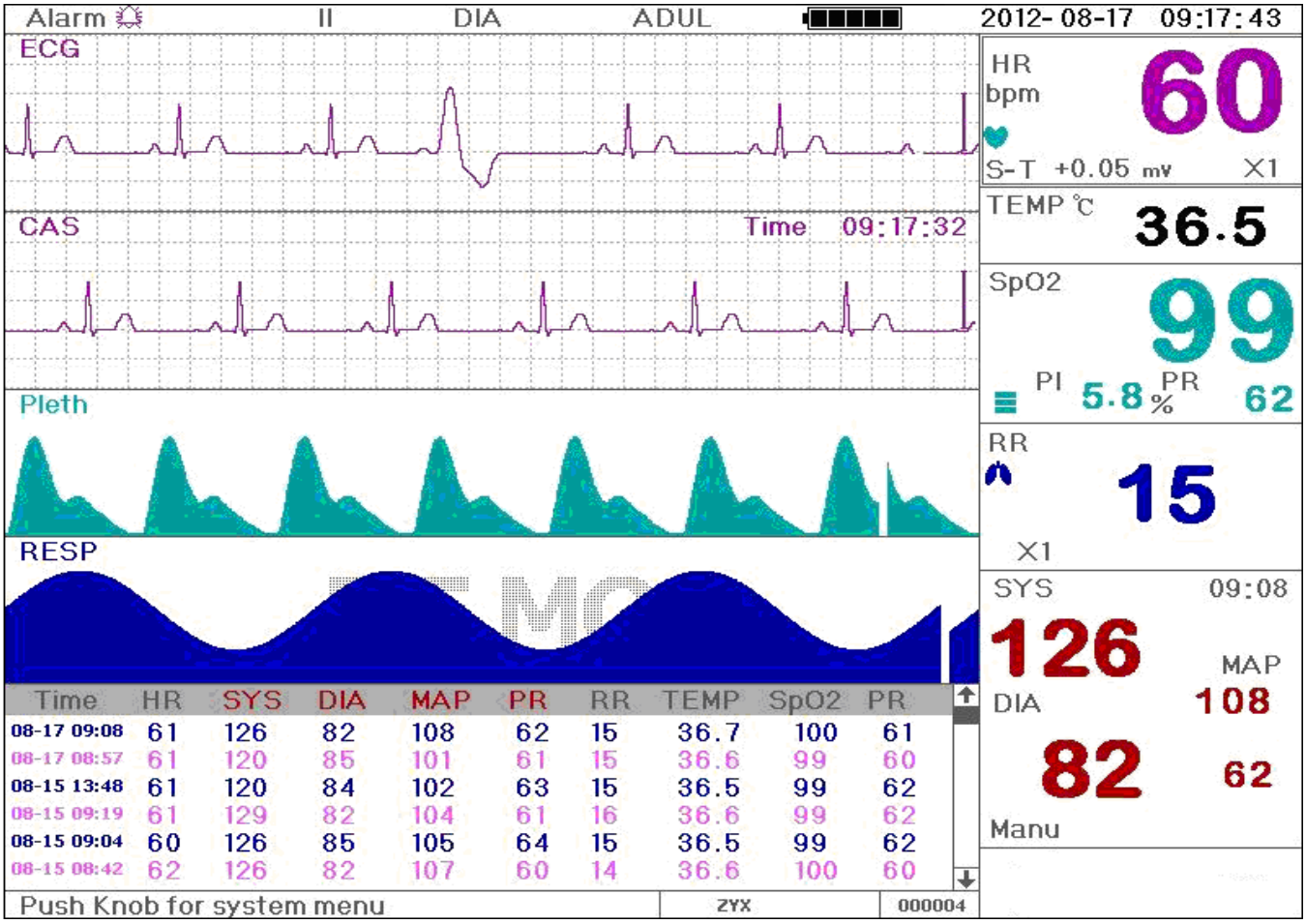


Figure 4.2 Main Screen

Navigation knob has two functions in main monitoring screen:

1. Long time press the navigation knob for about three seconds to enter system setup screen;
2. Rotate the navigation knob to focus the corresponding parameter area circularly by thick border, then short time press the knob for one second to enter corresponding parameter setup screen. That is to say, it is convenient to set each parameter's menu by this shortcut operation from the main screen.

Top line on the screen:

- ✧ **"Alarm 🔔":** Alarm status, green "🔔"shows the alarm ON，yellow "🔕" shows the alarm silence status. The alarm will be activated automatically after the end of given counting down or when a new type of alarm event occurs. Red "🔕" means the alarm sound is disabled when the sound volume is set to "0" in system parameter settings, meanwhile, the alarm sound is also off.
- ✧ **"II":** ECG Lead selection. I, II, III, aVR, aVL, aVF, V (V1-V6) and GND can be selected by LEAD switch.
- ✧ **"MON":** ECG Filter type. There are "Diagnosis", "Monitor", and "Operation" three types. The option can be set in the system setup menu.
- ✧ **"Adult":** The patient type. There are three selectable patient types: "Adult", "Infant" and "Neonate".

- **“ ”**: battery power indicator; when the indicator is yellow and displays only one “grid”, it means there is a little battery power left. When the indicator turns red and blinks, as well as less than one “grid” displays, meanwhile, the system alarm will be on to remind the battery shortage. Please connect the device to the mains power supply in time to ensure the normal use of this monitor, and the battery will be recharged. When the battery power is full, battery power indicator displays full grid. During recharging, the grids in the battery indicator are rolling circularly.
- **“2012-08-17 09:17:43”:** Current calendar time and date. The current Figure shows the time and date of August 17, 2012, 09:17:43.
- **“Push knob for system menu”:** System prompt or description for the current status.
- **“ZYX”:** Patient name. The patient name can be entered or changed in the archive management window.
- **“000004”:** The patient ID. The patient ID can be entered or changed in the archive management window.

Waveform area:

- 1st trace: The first signal trace is ECG waveform.
- 2nd trace: The second signal trace is cascade of the first ECG waveform. Notice the second trace is refreshed screen by screen, instead of consecutive refreshing in 1st trace. The start time “09:17:32” for 2nd trace is displayed on the upper right corner on the 2nd trace.
- 3rd trace: Respiratory waveform.
- 4th trace: SpO_2 plethysmograph.

Data area:

Figure 4.3 Heart Rate Data Area

- “**HR**”: Indicates the current display is heart rate. The 60 on the right side is the heart rate measured.
- “ ”: The heart- beating symbol. Its flashing corresponds to the R wave of the ECG waveform. The speed is the same as the heart rate.
- “**S-T +0.05mv**”: The measured milli-volts value during ST measurement.
- “**×1”:** ECG waveform gain (amplification), 6 options available:
  - “Auto” Automatic scaled waveform.
  - “×1/4” Waveform scaled with 1/4 of the basic gain.
  - “×1/2” Waveform scaled with half of the basic gain.
  - “×1” Waveform scaled with basic gain.
  - “×2” Waveform scaled with twice of the basic gain.
  - “×4” Waveform scaled with four times of the basic gain.

Figure 4.4 Temperature Data Area

- **"TEMP":** Temperature label. The value below "36.5" is the temperature values.
- **"°C":** Body temperature unit and value. When it shows (TEMP) °C, the temperature is in Celsius; when it shows (TEMP) °F, the temperature is in Fahrenheit.

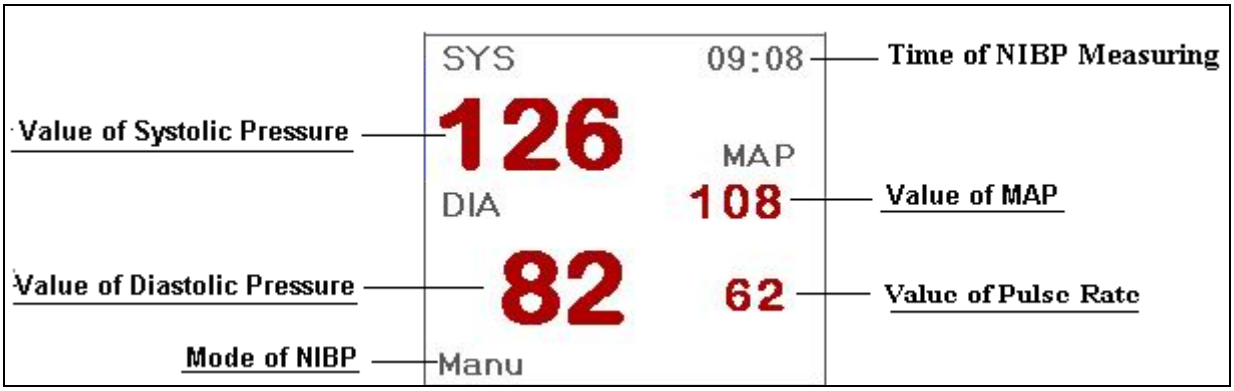


Figure 4.5 NIBP data area

NIBP Data:

- **"SYS", "DIA", "MAP":** The blood pressure type labels and the measured value.
- **"09:08":** The time of NIBP measuring.
- **"Manu":** The NIBP measurement mode: Manual mode.
- **"62":** Value of Pulse rate.

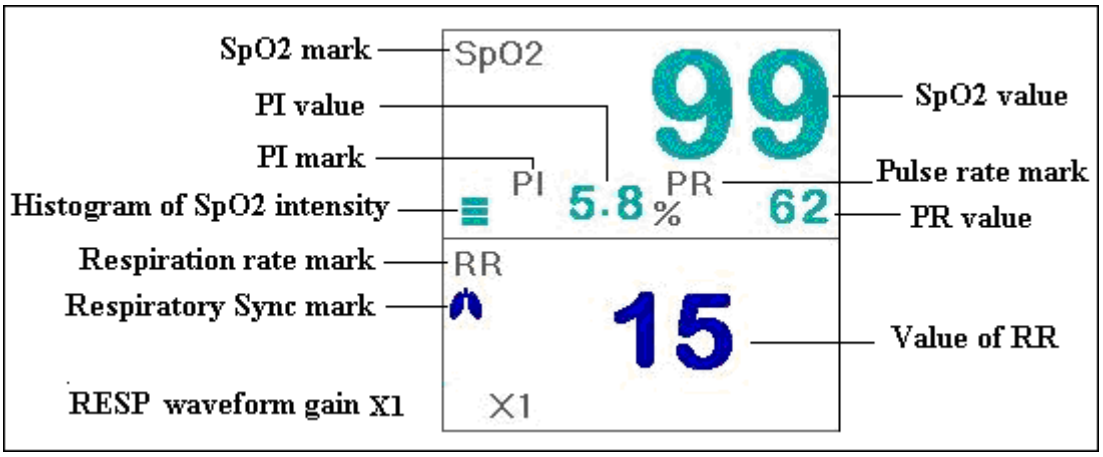


Figure 4.6 Respiration, SpO_2, PR Data Area

- **"SpO_2":** SpO_2 mark, the "99" on the right is the current SpO_2 value being measured.
- "**PI**": Perfusion index mark, "5.8%" is perfusion index value.
- **"":** SpO_2 intensity bar.
- **"PR":** Pulse rate label. The value "62" on the lower right shows the pulse rate value.

- ✧ **“RR”:** Respiration Rate: The bpm after that is the unit of the respiration, i.e., beat per min. When there is no respiration wave detected, the screen will display “in searching”.
- ✧ “ ”**:** Respiratory Sync mark, it is synchronized with respiratory waveform.
- ✧ “**15**”: Respiration rate
- ✧ **“×1”:** Respiration gain（amplification）:

  “×1/2” Waveform scaled with half of the basic gain.

  “×1” Waveform scaled with basic gain.

  “×2” Waveform scaled with twice of the basic gain.

  “×4” Waveform scaled with four times of the basic gain.

NIBP List:

Below the operating area is the data list area, as shown in Figure 4.7.

Time	HR	SYS	DIA	MAP	PR	RR	TEMP	SpO2	PR
08-15 08:42	62	126	82	107	60	14	36.6	100	60
08-06 14:08	62	127	85	109	62	16	36.6	99	61
07-27 09:29	60	120	89	106	62	16	36.7	100	61
07-27 09:27	62	126	87	107	63	15	36.7	100	60
07-27 09:25	61	125	83	109	61	15	36.7	99	62
07-27 09:05	62	129	82	103	63	15	36.6	99	62

Figure 4.7 NIBP List Area

The time stamp is the time when the NIBP measurements are taken. The data lists here are different under different operating mode. As shown in Figure 4.7, one screen of the data list can list up to 6 groups of data. When there are more than 6 groups of data, we can rotate the navigation knob to scroll the complete list.

4.2 Display2 Screen

4.2.1 Viewing Screen

Choose Obsev of Disp2 on system setup screen, press the DISP key to enter the monitoring screen, as shown in Figure 4.8.

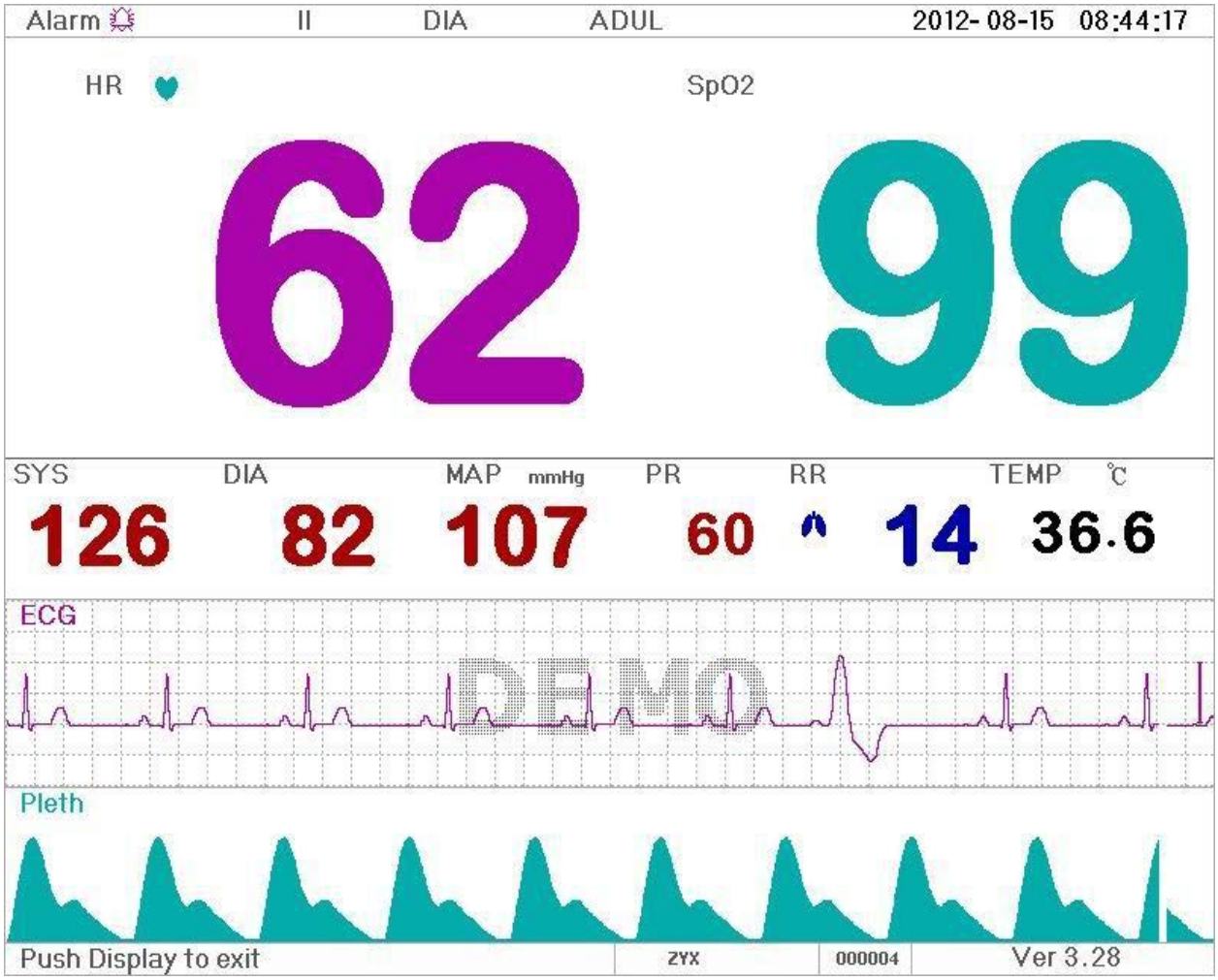


Figure 4.8 Viewing Screen

In this screen, press the DISP key to switch the ECG lead, or press the Print key to print the ECG waveform and the second waveform. The second waveform can be selected in the System menu.

4.3 Freeze and ST Analysis Screen

In the main screen, press the Freeze key to freeze three channel ECG waveforms or all the waveforms on the screen, as shown in Figure 4.9.

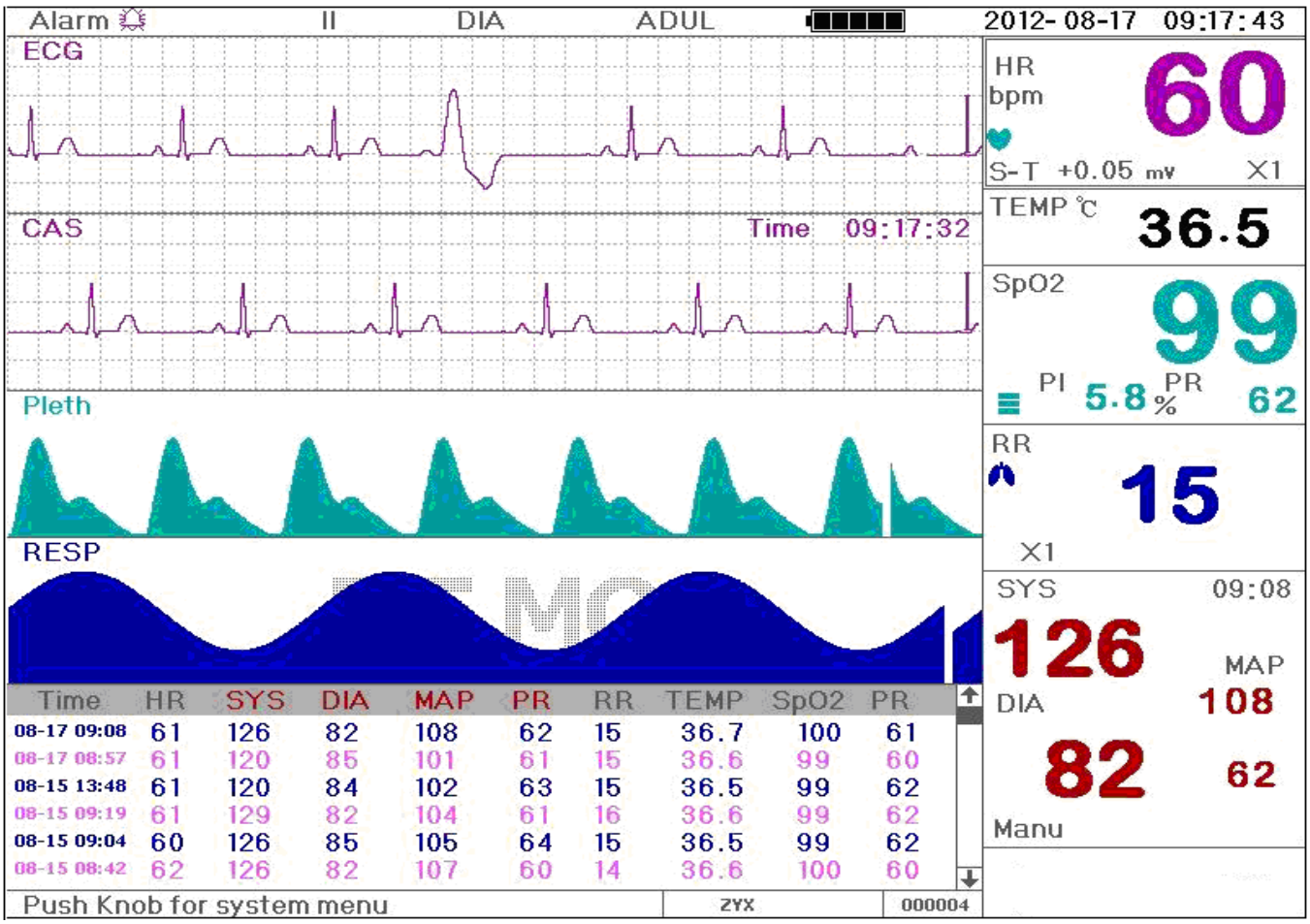


Figure 4.9 Frozen Screen

4.3.1 Screen Description

Freezing, ST segment analysis screen is similar with the main screen, except that the waveforms are frozen. For example, the Figure 4.10 is a portion of the frozen waveform. The symbols on the screen are described briefly on the screen.

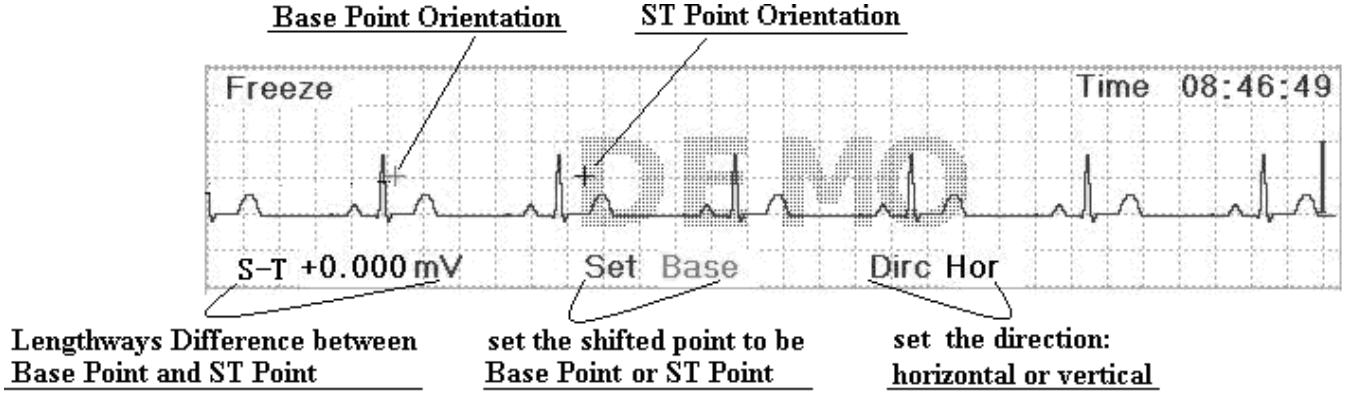

Base Point Orientation
ST Point Orientation
Freeze
Time 08:46:49
S-T +0.000 mV
Set Base
Dirc Hor
Lengthways Difference between Base Point and ST Point
set the shifted point to be Base Point or ST Point
set the direction: horizontal or vertical

Figure 4.10 Frozen Waveform

When the system setting for the freezing waveform is "ALL", the Freeze key will freeze all the waveforms.

4.3.2 Operation Instruction

The operator can use the Navigation Knob to analyze the ST segment waveform, i.e. measuring the difference between the ST segment value and the referenced value. The value is displayed after the measure on “S-T + 0.000 mV”. The operation is carried out in 4 steps.

First, rotate the Navigation Knob to move the base point (the red cross) horizontally to base line point (the base line is between the Q wave and the P wave). At this point, the frozen screen shows “S-T+0.xxx mV, Set Base, Dirc Hor”.

Second, press the Navigation Knob. The screen shows “S-T+0.xxx mV, Set Base, Dirc Ver”. Then rotate the knob to move the base point vertically to the base line point.

Third, press the Navigation Knob again. The screen shows “S-T+0.xxx mV, Set STDot, Dirc Hor”. Rotate the knob to move the ST point (the yellow cross) horizontally to the point to be measured on the ST segment.

Last, press the Navigation Knob again. The screen shows “S-T+0.xxx mV, Set STDot, Dirc Ver”. Rotate the knob to move the ST point vertically to the point to be measured on the ST segment.
One the main screen allows pressing the freeze key to enter the ST segment analysis screen.
NOTE: The S point is the end point of S wave, and the T point is the start point of T wave.

4.4 Mode Selection Screen

Press the Navigation Knob in the main screen as shown in Figure 4.2, the operating area shows the mode selection screen, as shown in Figure 4.11.

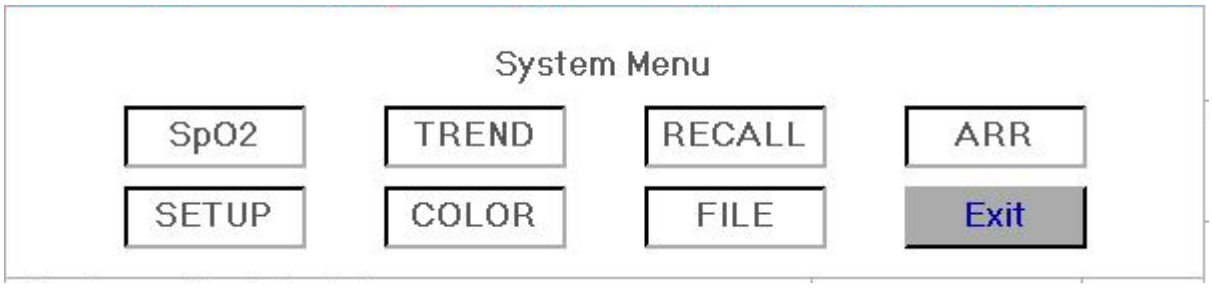


Figure 4.11 Trend Menu Screen

In the mode selection screen, rotate the knob to move the gray cursor to the corresponding screen. Press the knob to enter the screen of SpO_2, Trend, Recall, ARR, Setup, Color and File. The following sections from chapter 4.5 will describe each one of the 7 screens. If you want to exit from this screen, press the Display Key.

4.5 SpO_2 Data List Screen

Move the gray cursor to SpO_2 List in the mode selection screen, and press Navigation Knob to enter SpO_2 data list screen, displays in the same position shown as Figure 4.12.

Time	HR	SYS	DIA	MAP	RR	EtCO2	SpO2	PR
07-22 14:05	61	122	88	106	15	40.5	100	62
07-22 14:05	62	122	88	106	14	39.7	99	62
07-22 14:05	60	122	88	106	14	38.3	100	62
07-22 14:05	60	122	88	106	16	39.4	99	60
07-22 14:05	60	120	82	103	16	38.3	100	61
07-22 14:05	60	120	82	103	15	40.0	99	60

Figure 4.12 SpO_2 List

4.5.1 Screen Description

In the SpO_2 list title bar, the front color of SpO_2, Pulse is the same as SpO_2 parameters' while other front color is white.

The operation on the data listing is simple. Using the Navigation Knob allows the user to scroll the list up and down. When rotating the knob anti-clockwise, the list scrolls upward (i.e. use the ↑ arrow to scroll the data). When rotating knob clockwise, the list scrolls down (i.e. use the ↓ arrow to scroll the data).

All the parameters in the SpO_2 data list are corresponding to the time when the SpO_2 measurements were taken. There is only one record every 4 seconds.

4.6 Trend Screen

4.6.1 Screen Description

Move the gray cursor to the "Trend" button, press the knob, you will get the trend menu screen as shown in Figure 4.13.

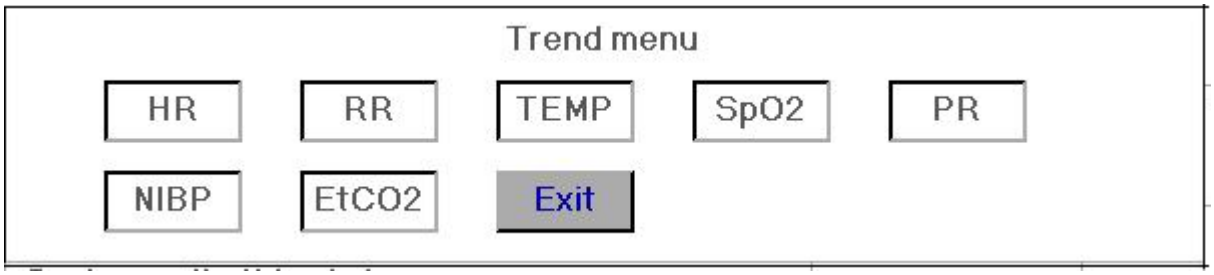


Figure 4.13 Trend Menu

If you want to enter one of the trend graphs, the procedures are: rotate the knob, move the cursor to one of the parameter. For example, from the left to right, we are entering "Heart Rate", "Respiration Rate", "Temperature", "SpO_2" and "NIBP" trend graphs. Theses screens are described in the following Figures.

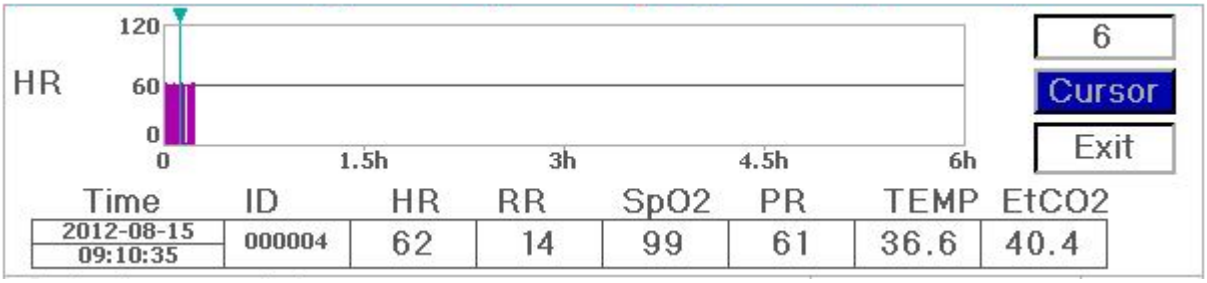


Figure 4.14 Heart Rate Trend Graph

Figure 4.14 is the heart rate trend graph. There are 3 options on the right of the graph, as described below.

The "6" on the top shows the trend graph time. Move the cursor to the trend time, press the knob and rotate it, and the trend graph time will change to 24, 120 or 480, which changes the horizontal coordinates to be 24 hours, 120 hours or 480hours. The corresponding trend graph also changes to 24 - hour trend, 120 - hour trend or 480 - hour trend.

After choosing "Scan", the trend graph display a triangle and a vertical line. This is a moving data marker. As shown in the picture, when you move the marker to a specific point, the data area below the graph will display the marker's time, and its corresponding patient ID, heart rate, respiration rate, SpO_2, temperature. When rotating the knob to move the marker, the moving interval is a changing value. The rule is as following: the initial step is 1. After you move towards the same direction 5 times, the interval becomes 5, after 5 more steps, the interval becomes 10, and therefore it can go to 20, 40. No matter what your interval is, as soon as you move toward the other direction, the interval becomes 1 on

the other direction. Therefore, it is very easy to find the time you are looking for.

The last button is “Exit”. Move the cursor to the Exit button, and press the knob to return to the previous level screen. The screen returned to the Trend menu screen as shown in 4.13.

Please note that the max value on the vertical axis of the ECG is 120, not the max value of the ECG upper limit. The scaled down graph provide better waveforms. When the ECG value exceeds 120, the vertical axis max value will automatically change to 240. The three value to change to 0, 120, 240 from 0, 60, 120 for reference. When system gets reset or the patient ID has changed, the vertical axis will return to its original value of 0, 60, and 120. Other changes of vertical axis value in other trend graph are similar to that of ECG.

The Trend graph shows parameter value of the current time. For example, in the 6 hours trend graph, when the monitoring time exceeds 6 hours, the trend graph will move toward the right and the data 6 hours ago will be moved out of the graph. This ensures the screen always displays the current data for review. The data moved out of the graph is not deleted, they are just hidden temporarily. When the time frame changes from 6 hours to 24 hours (while the monitoring time is less than 24 hours), the complete set of data will display. Other trend graph follows the same rule.

The respiration rate, body temperature and other trend graph are similar to that of ECG trend graph and we will not cover them in detail again. Please note that for those trend graphs, the horizontal axis unit is number of time the blood pressure is measured instead of time. NIBP graphic trend is a little different from the other graphic trends. Rotate the knob to move the cursor to “ << >> ”, then press the knob for activating this item. Next, rotate the knob towards left or right for viewing another 400 groups’ graphic trend.

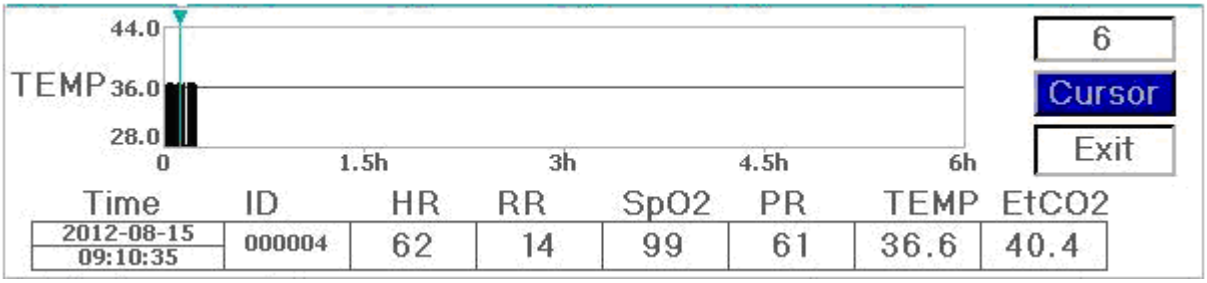


Figure 4.15 Body Temperature Trend Graph

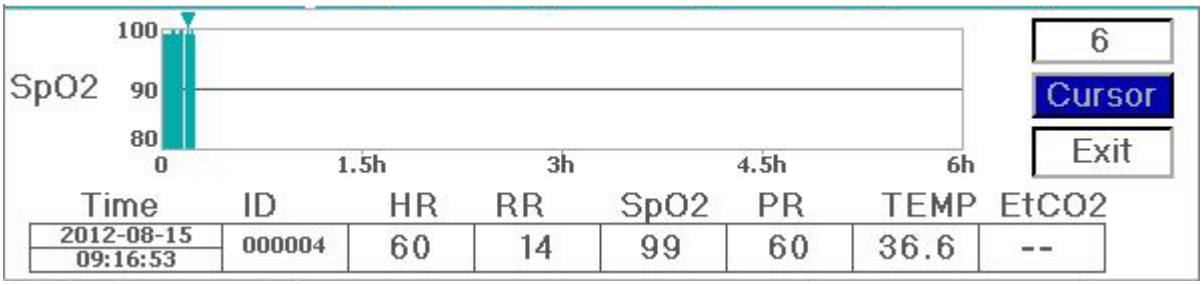


Figure 4.16 SpO_2 Trend Graph

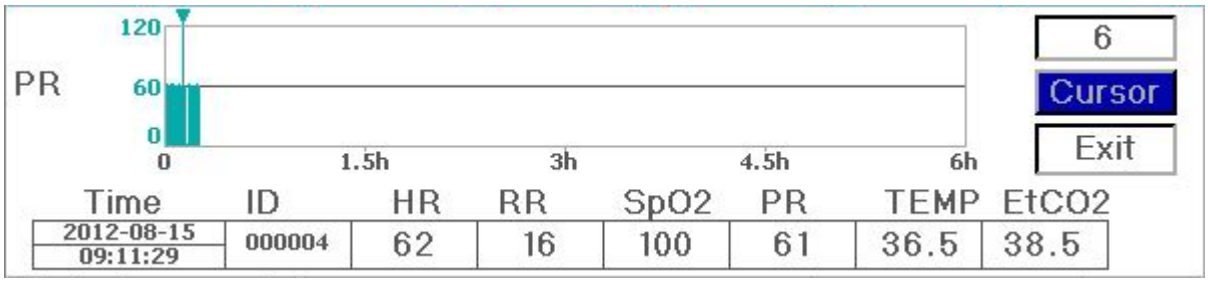


Figure 4.17 Pulse Rate Trend Graph

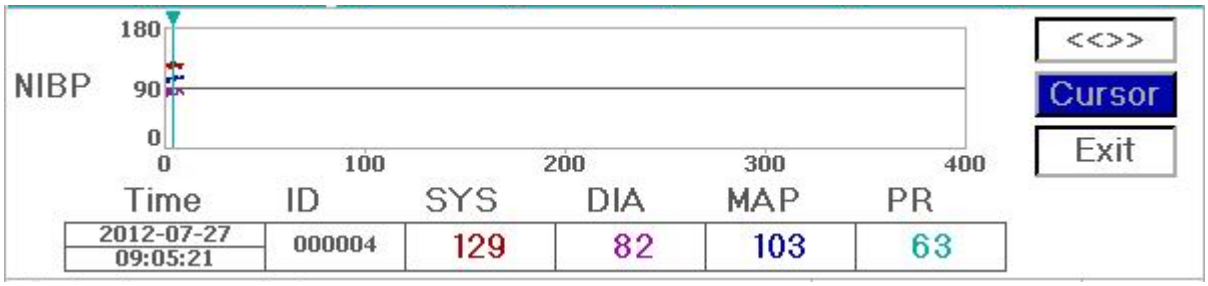


Figure 4.18 NIBP Trend Graph

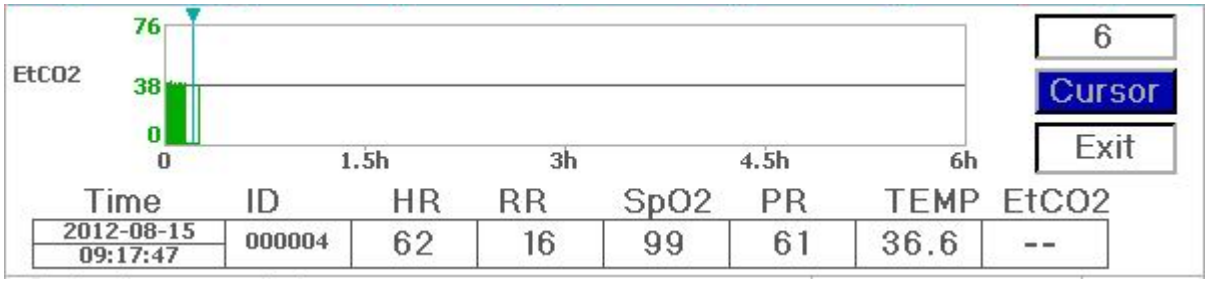


Figure 4.19 $EtCO_2$ Trend Graph

4.6.2 Operating Instructions

Rotate the knob, choose the parameter and press the knob. Review the trend graph and move the cursor to the Exit button to exit the trend graph.

4.7 Recall Screen

Move the cursor to “RCALL” in the mode selection screen and press the navigation knob, the system enters in the waveform recall screen.

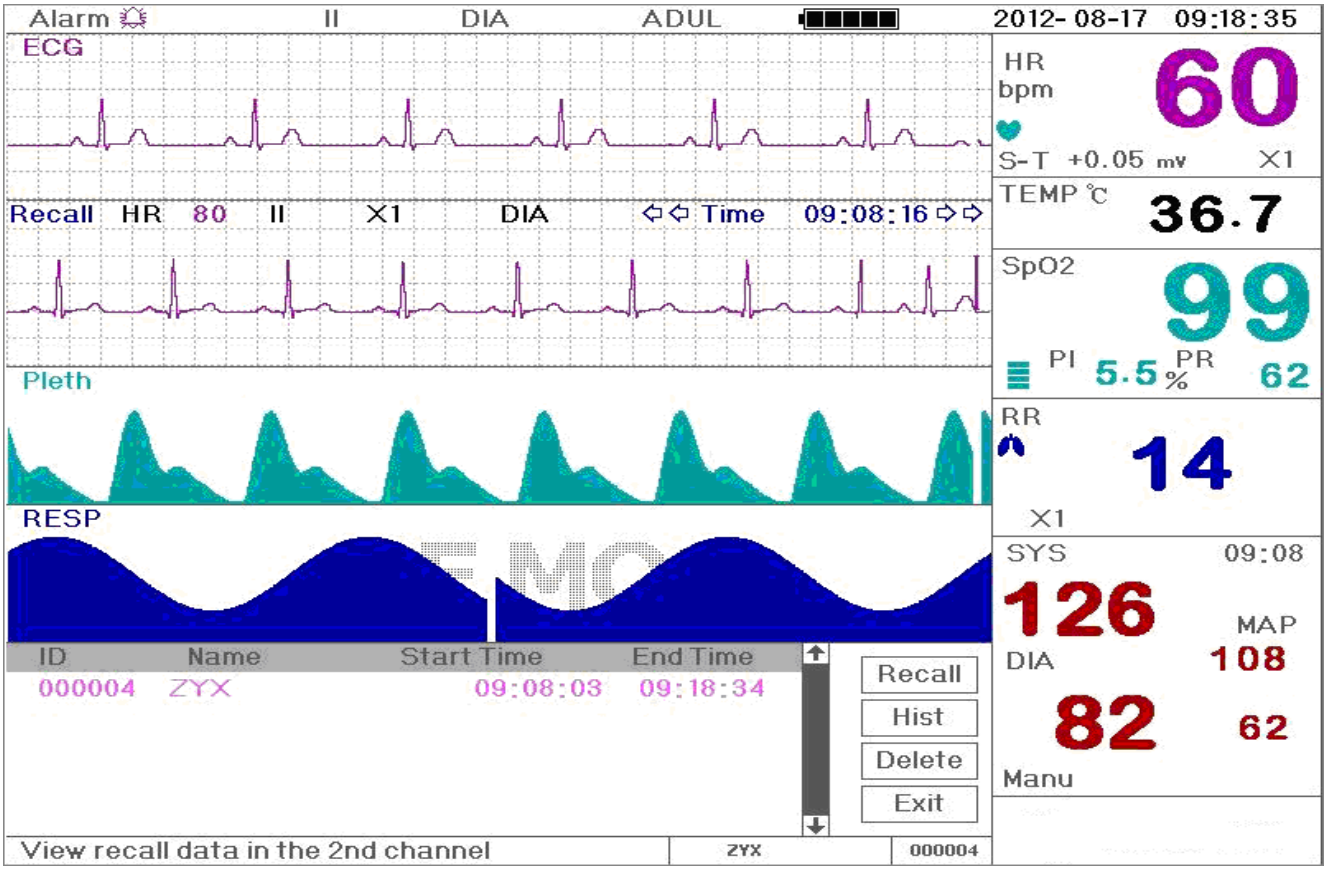


Figure 4.20 Waveform Recall Screen

The waveform recall screen is shown in Figure 4.20. It is different from the main screen in its 2nd waveform area and the operation area. We will cover them in detail below.

Figure 4.21 Recall List

Rotate the knob and choose “Recall”, “HIST”, “Delete” and “Exit” button. We explain each button’s function below.

Recall: press the Recall button; the first list on the recall listings becomes highlighted. Rotate the knob to choose the record. Press the knob to perform the recall. The recalled waveform displays on the 2nd channel of the waveform area, as shown in Figure 4.22.

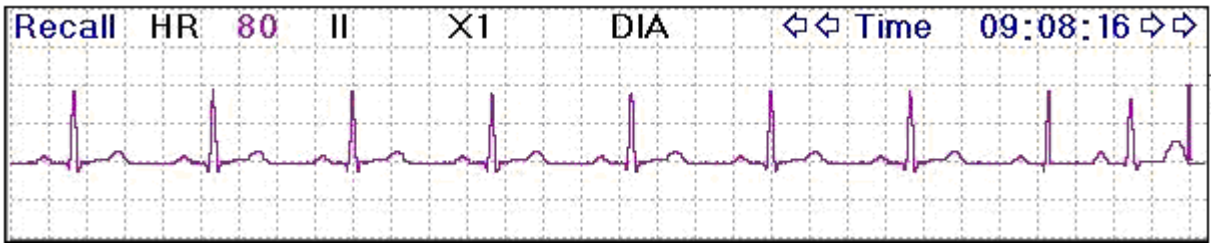


Figure 4.22 Waveform Recall

Rotate the knob to move forward and backward of the recalled waveform. Press the knob to exit the waveform recall and return to the initial state of the waveform recall screen.

During waveform recall, the system not only displays the current recalled waveform, it also displays the lead status, gain and filter type for the waveform.

HIST: press this button to switch the button between the history button and current button. Press the History button the recall listing on the left side displays the history listing. Press the Current button, the recall list on the left side displays the current listings. When entering the recall screen, the system defaults to the current listing.

Delete: press this button, the record on the recall list become highlighted. Rotate the knob to choose the record being deleted. Press the knob and hold for 2 seconds and release the knob. The record will be deleted. The current record cannot be deleted.

Exit: press this key to return to the system setup menu.

In this screen, the system can print the recalled data or the recalled waveform.

4.8 ARR Screen

Move the gray cursor to “ARR” and press Navigation Knob to enter ARR screen, shown in Figure 4.23. The structure is similar to recall screen. We will cover each function key below.

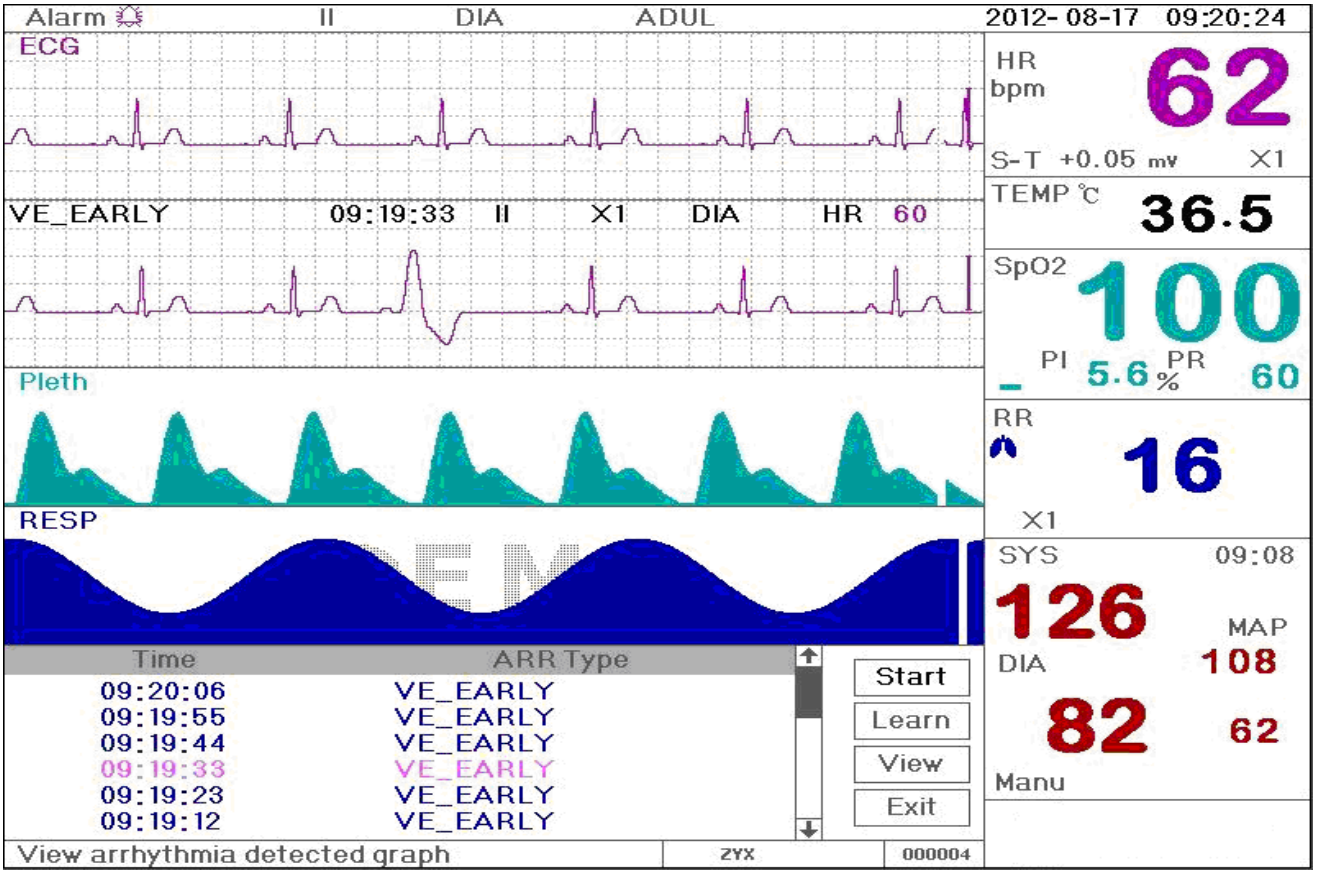


Figure 4.23 Screen with ARR Detection

Start: This button is used to start and end the system arrhythmia detecting function (short for ARR). This function is disabled initially by default. When the ARR is not ON, the “Learn” key is disabled. Press this key, then the device enters learning mode and the “Start” changes to “Close”. Press it again to end the learning. When “Learn” key change to yellow from gray, it indicates the learning has finished. When the arrhythmia detection begins, the device will automatically detect the arrhythmia waveforms. If arrhythmia is detected, the arrhythmia waveform will be displayed in the second signal trace, shown in Figure 4.23.

When the device gets reset or the patient is changed, the arrhythmia needs to be re-learned.

Learn: Because the arrhythmia detection is based on the pattern of normal ECG waveform at the same speed and with the same amplitude, when the patient is changed, or the arrhythmia detection is incorrect, the arrhythmia detection needs re-learn to build up pattern. To better use the learn function, it is recommended to use a good ECG waveform for learning during the monitoring.

Exit: press this key to exit the arrhythmia detection screen and return to the system menu.

During monitoring, if arrhythmia is detected, the system will alarm. The ARR alarm is system default and does not need setup.

During arrhythmia detection, incorrect detection might occur if the non-ECG waveforms (e.g.; square wave and triangle wave) appear.

Before start 1mv testing, please turn off the ARR detection.

During arrhythmia detection, the arrhythmia module is very important. The system requires a group of stable ECG waveforms. If the system detects the arrhythmia incorrectly, please make sure the correct ECG model is used. Otherwise please re-learn arrhythmia.

4.9 The Menu Setup Screen of the System

4.9.1 Screen Description

During the Mode Selection screen, move the cursor to the “SETUP” and press the knob. The screen shows the system setting screen as shown in Figure 4.24.

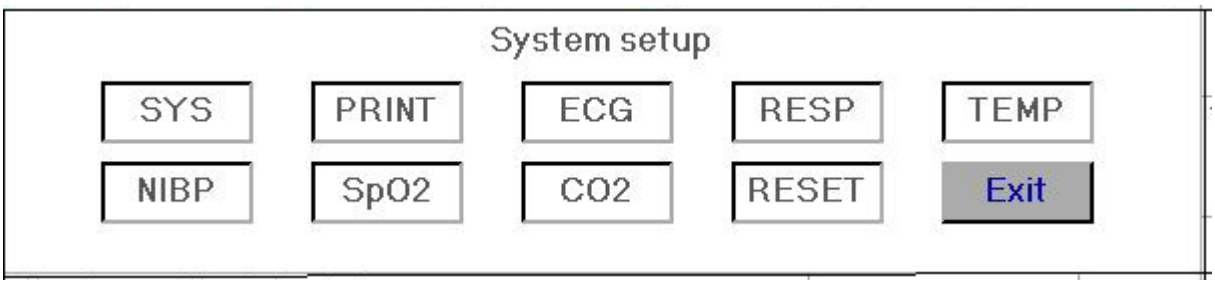


Figure 4.24 System Settings

To set up the system parameter, rotate the knob and move the cursor to the corresponding button, press the knob to perform the corresponding system settings.

Press the DEF button will make settings returned to the factory default and will not change the patient document and the recalled data. Our instructions will cover the functions of each button.

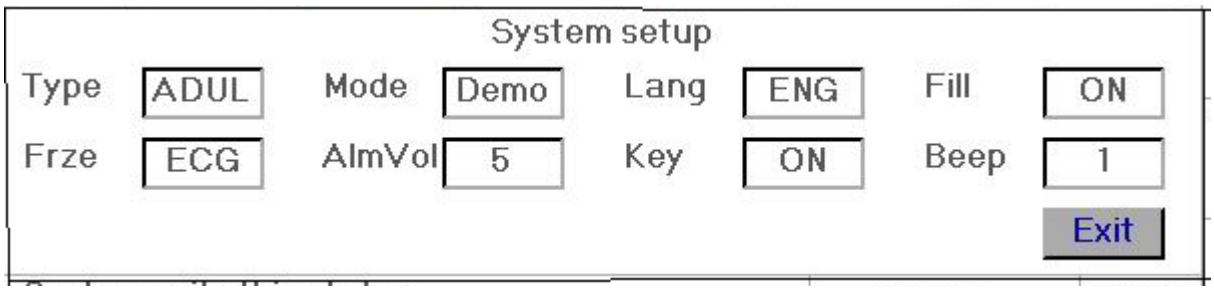


Figure 4.25 System Parameter Settings

4.9.2 System Parameter Settings

Type: The subject being monitored, this can be chosen among Adult and Infant patient.
The factory default is “Adult”
When changing the patient type, the system will perform initiation of the alarm settings, NIBP settings. Please pay special attention to the patient type before starting the monitoring. It is strictly forbidden to use Adult type on the infant patient. Doing so can cause serious injury.

Mode: Monitoring mode selection. The “Real” shows the real time waveform, i.e. normal monitoring state. The DEMO shows the demo waveforms. During the demo state, all the signals and data are generated from the patient monitor for demo and testing purpose. The factory default is “Real Time”.

Lang: for setting the display language. The patient monitor is equipped with dual-language, the primary and secondary languages, which can be switched alternatively by user. The default language configuration is "ENG" (English) as the primary language, "中文" (Chinese) as the secondary language. The available secondary languages can be configured optionally with "中文" (Chinese), "ENG" (English), "PTG" (Portuguese), "CSK" (Czechish), "TRK" (Turkish) and "FRA" (French). For the special configuration without the secondary language, the display language is always "ENG" (English), and this setting item is gray so that it can not be set.

Fill: When the fill setting is ON, the display fills the volume for the SpO_2 and Respiration. When it is OFF, the system displays the line graph. The default is OFF.

Frze: Freeze controls the waveforms being frozen when the Freeze button is pressed. The options are “All” and “ECG”. When ECG is selected, the system only freezes the ECG waveform. When “All” is selected, the system freezes all the waveforms including ECG, SpO_2, and Respiration. The factory default is “ECG”

Print: PC42 is the type of the built-in printer, can not be adjusted.

Timer: The timer is the time setting for timed printing when the printer setting is ON. The unit is minutes. The options are “OFF, 1, 2, 3… 240”. OFF shows the no timed printing. If a timed minute is selected, the printer will print the current data/waveform at the preset interval specified at the timer. The factory default is OFF.

Wav2: The second waveform to be printed when the Printer setting is internal printer PC42. The options are pleth (SpO_2), Respiration. The default is SpO_2.

ARR: the setting for arrhythmia trigged printing when the Printer setting is ON. If ARR is ON, during the ARR screen, the arrhythmia will trigger the printing of the arrhythmia waveform. The factory default is OFF.

Vol: The sound volume. The max volume is 7 and the min is 0, i.e. no sound. The factory default is 5.

Key: keystroke sound. The factory default is ON.

4.9.3 ECG Parameter Settings

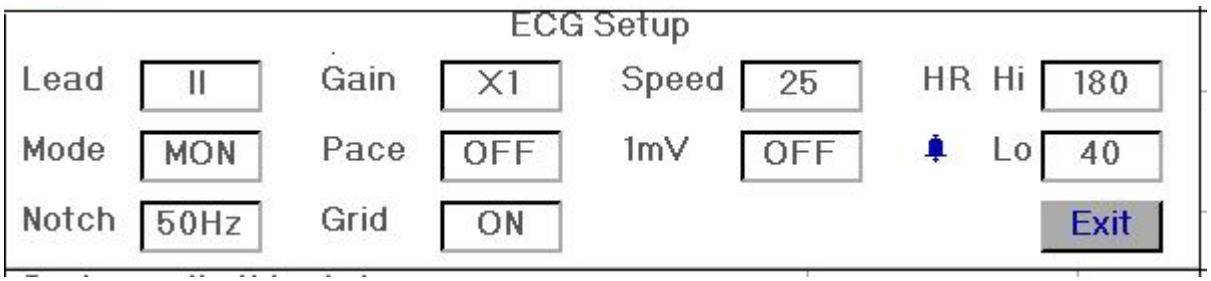


Figure 4.26 ECG Settings

- ✧ **Lead:** Can choose from I, II, III, AVR, AVL, AVF, V (V1-V6), and GND. The factory default is II.
- ✧ **Gain:** The ECG gain, 6 options ×1/4, ×1/2, ×1, ×2, ×4 and Auto. Auto is for automatic gain control. The factory default is ×1.
- ✧ **Speed:** ECG waveform sweeping. 4 options: 6.25, 12.5, 25, 50 mm/s. The factory default is 25 mm/s.
- ✧ **HR Hi:** Heart rate upper alarm setting

  Lo: Heart rate lower alarm setting

  The adjustable range and the factory default value can be found in Chapter 11.
- ✧ **Mode:** ECG filter mode. Three options: MON, DIA, and OPE.

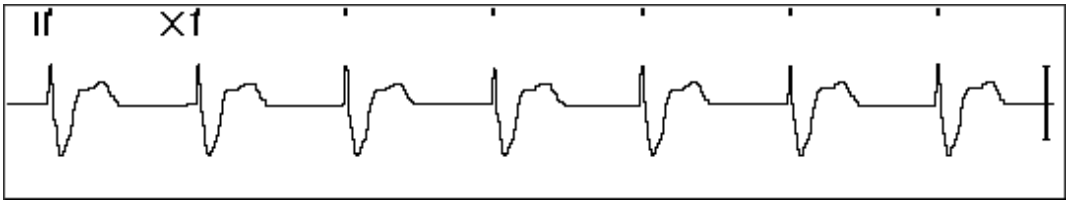
  MON: Monitoring mode, moderate filtering. It can filter out interference and present good ECG waves.

  DIA: Diagnosis. No filtering. It represents the true ECG without filtering.

  OPE: Operation. Deep filtering. It can filter out strong interference.

  The factory default is MON.

- ✧ **BtSnd:** Heart beat sound. The synchronous heart beat sound during monitoring. The factory default is ON.
- ✧ **1mV:** Generating the 1mv signal. This signal is used to test the function of the machine. It is not used during normal operation. Factory default is OFF.
- ✧ **Notch:** frequency filter. Different hardware configuration may make its options various. One is “ON” or “OFF” (The factory default is ON.), and it means turn on or turn off the 50Hz frequency filter. The other option is “OFF”, “50 Hz” or “60 Hz”, please choose “50 Hz” or “60 Hz” frequency filter according to your power supply frequency. The factory default is “50 Hz”.
- ✧ **Pace:** Cardiac pacemaker detection. When Pace is “ON”, a mark will be displayed on the ECG waveform if the patient fitted with a cardiac pacemaker. The factory default is OFF.



- ✧ **Grid:** The grids will be displayed on the background if this setting is “ON”. The factory default is ON.

Move the cursor to the upper or lower limits of the alarm settings, and press the Alarm key to turn ON and OFF the alarm for the setting. Yellow color shows ON status, and gray color show the OFF status.

4.9.4 Respiration Parameter Settings

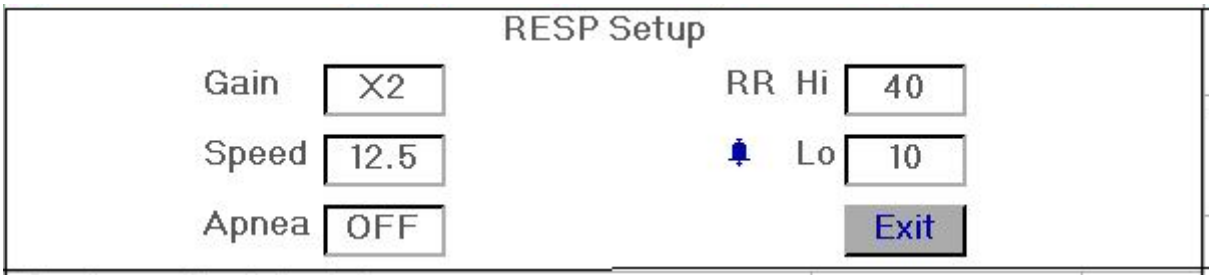


Figure 4.27 Respiration Settings

- ✧ **Gain:** Respiration amplification/gain, 4 options, ×1/2, ×1, ×2, ×4, the factory setting is “×2”.
- ✧ **Speed:** Respiration display speed. 2 options 6.25mm/s and 12.5 mm/s. The factory setting is 12.5 mm/s**.**
- ✧ **Apnea:** The apnea alarm time (in second), the specified time is 5-120 seconds. When the patient stop breathing for the time longer than the specified second, the Respiration display channel display warning “Apnea xxx second”. When the apnea time exceeds 250 seconds, the system stops the timing and displays “Apnea ***”.
- ✧ **RR Hi**: Respiration rate upper alarm setting, adjustable 1 – 120 bpm.

  Lo: Respiration rate lower alarm setting, adjustable 0 – 119 bpm.

4.9.5 Temperature Parameter Settings

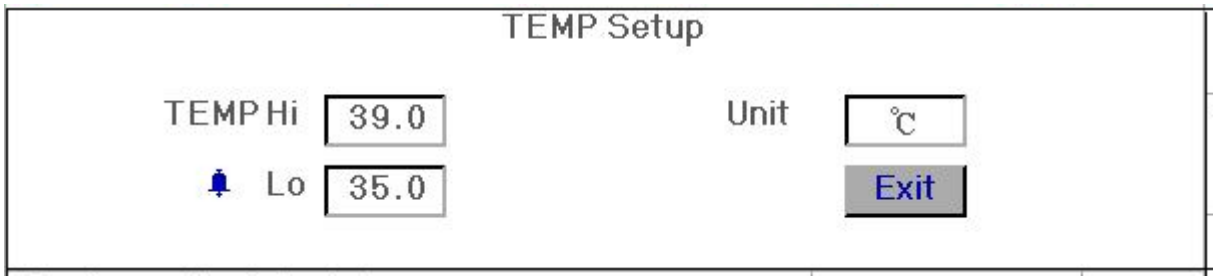


Figure 4.28 Temperature Settings

✧ **TEMP Hi：** Temperature 1 upper alarm setting, adjustable 0.1 – 60.0°C (32.1 - 140.0°F)

Lo： Temperature 1 lower alarm setting, adjustable 0 – 59.9°C (32.0 - 139.8°F)

✧ **Unit：** Temperature unit. The factory setting is °C (Celsius) and can be set to °F (Fahrenheit).

4.9.6 NIBP Parameter Settings

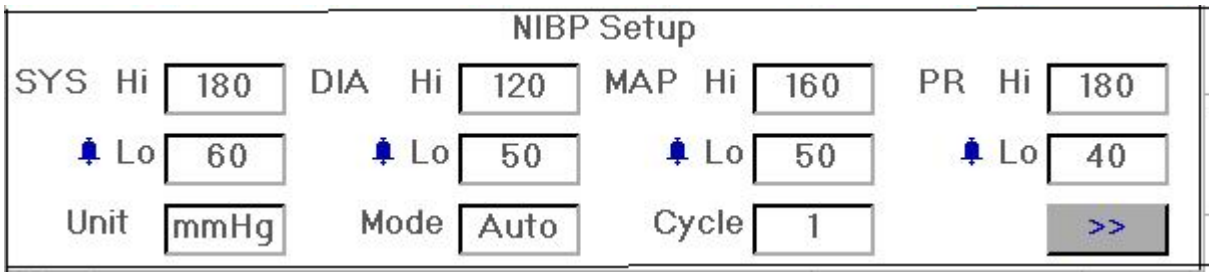


Figure 4.29 NIBP Settings(1)

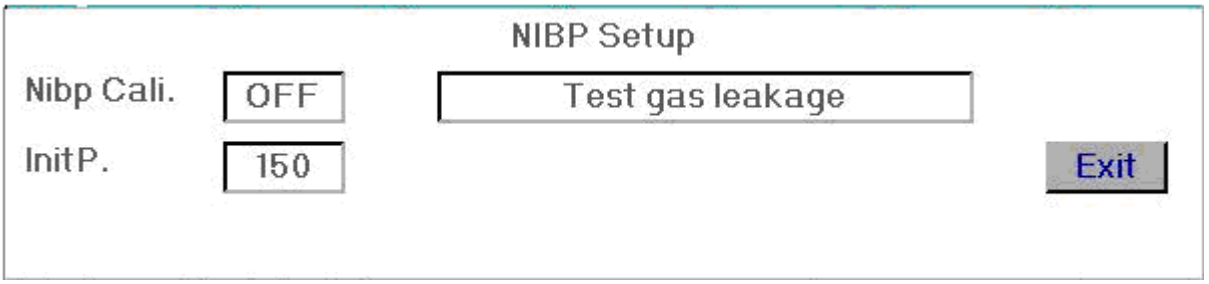


Figure 4.30 NIBP Setting(2)

NOTE: NIBP Setup Screen will be displayed in two pages (As shown in Fig 4.29 and Fig 4.30). Move the gray cursor to " ", then press the navigation knob to enter the second page where three operations: "NIBP calibration", "Test gas leakage" and "Initial pressure" can be conducted.

✧ **SYS Hi/Lo:** Systolic pressure upper and lower alarm limits.

✧ **DIA Hi/Lo:** Diastolic pressure upper and lower alarm limits.

✧ **MAP Hi/Lo:** Mean arterial pressure upper and lower alarm limits.

✧ **PR Hi/Lo:** Pulse rate upper and lower alarm limits.

✧ **Unit:** the pressure unit. mmHg or kPa. The factory default is mmHg.

- ✧ **Mode:** The cuff inflation mode, manual or automatic. The factory default is manual. The operator needs to press the NIBP button to perform NIBP measurement. If the Auto mode is chosen, the operator needs to choose a cycle time as well.
- ✧ **Cycle:** The inflation interval when the NIBP measurement is set as Auto. The options are STAT, 1 min, 2 min…480min.

  WARNING: STAT can only be used for Adult. Using this mode to Infant patient can cause serious injury.
- ✧ **NIBP Cali:** It is used to check the accuracy of pressure measuring system within NIBP module, which should be conducted by technicians in test house or service department. There are three options: “Mode 1”, “Mode 2” and “OFF” available. After the calibration, it is necessary to manually confirm it is in “OFF” status again, or other operations can’t be carried out and NIBP key will be disabled. Factory default status is “OFF”.
- ✧ **Air leakage test:** it is used by technicians to perform a leakage inspection for NIBP pneumatic system.
- ✧ **Initial inflation pressure setup:** Cuff pressure to be inflated initially, its range is different depending on patient type.

  for neonates: initial inflation pressure: 60, 70, 80mmHg, default setting: 70 mmHg;

  for infants: initial inflation pressure: 80, 100, 120, 140 mmHg, default setting: 100 mmHg;

  for adults: initial inflation pressure: 80, 100, 120, 140, 160, 180, 200mmHg, default setting: 150 mmHg.

4.9.7 SpO_2 Parameter Settings

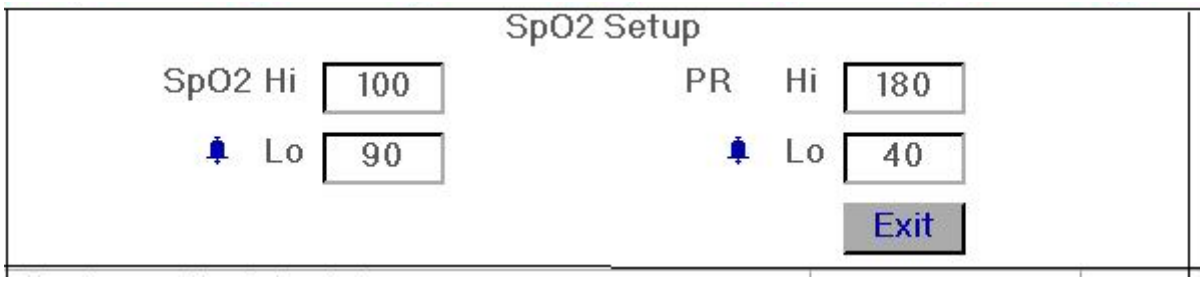


Figure 4.31 SpO_2 Settings

SpO_2 Hi/Lo: SpO_2 upper and lower alarm settings, adjustable 1-100/0-99.

Pulse Hi/Lo: Pulse rate upper and lower alarm settings, adjustable 21-250/20-249.

4.9.8 Resume Default

System parameters default key. Move the cursor to “DEF”, press the Navigation knob for 2seconds, all the value of parameters will resume default except the setting of language and printer type.

4.10 Color Setting Screen

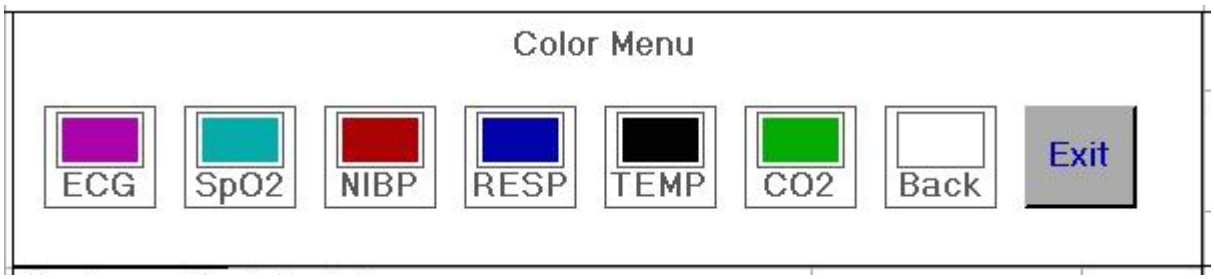


Figure 4.32 Color Setting Screen

In this screen, rotate the knob to choose the color, press the knob and rotate it to change the color. When the appropriate color is chosen press the knob again to save it.

Press the Exit to exit this color settings screen.

Only the background color (BACK) can use the color black. The background color can not be the same as other color.

4.11 Document/Patient Management Screen

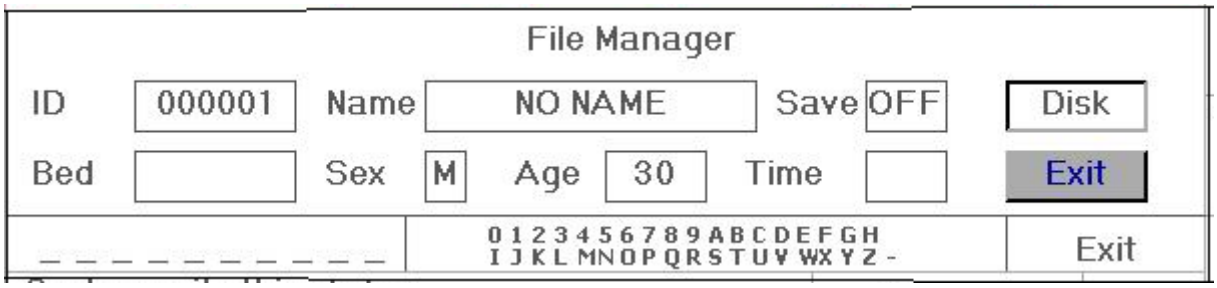


Figure 4.33 Document Management Screen

The document/patient management screen can be used to manage information about the patient. In the screen, the operator can enter the patient ID, name, bed number, sex, and age. The operator can also choose to save the patient data in the permanent storage. The screen is shown in Figure 4.33.

ID or Patient ID. To enter patient ID, choose the patient ID field using the rotate knob. Press the rotate knob to enter the text entry box. Rotate the knob to choose the letter and press the knob to enter the letter. To delete the letter, move the cursor to the letter to be deleted and rotate the knob to enter spaces (after the Z). Use the spaces to replace the letters. After finishing entering the patient ID, choose Exit button and press the knob to exit the text entry. The patient ID is the unique identifier for the patient. When the patient ID changes, the system considers the patient has changed.

Name: Enter the patient name.

Bed: Enter the bed number.

Sex: Choose between M or F for male or female.

Age: Choose the age field and use the rotate knob to select an age.

Save: The operator can choose how much of the data that needs to be saved. The unit is hour. Once the time is chosen, the system starts to save data from the current time. The factory default is OFF.

Time: Use the Navigation Knob to set the time of data saved. Save is not available if the Time is 0.

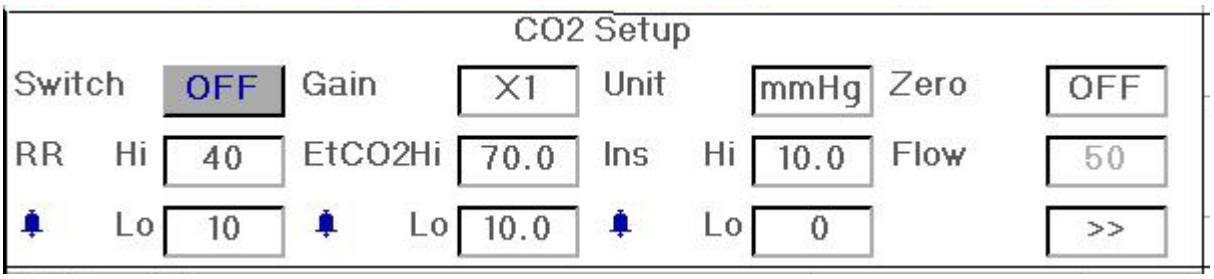
Disk: Move the cursor on “Disk”, press the Navigation Knob to read the information of Disk.

Chapter 5 CO_2 Monitoring

If your monitor has CO_2 monitoring function, please follow the instructions in this chapter to perform CO_2 monitoring on patient. The parameter setting menu and monitoring menu differ from different models, please refer to the monitor on hand.

5.1 CO_2 Parameter Settings

1. On Main Screen, press the knob to enter System Menu Screen. Then choose "SETUP→CO_2"to enter CO_2 Parameter Settings screen.



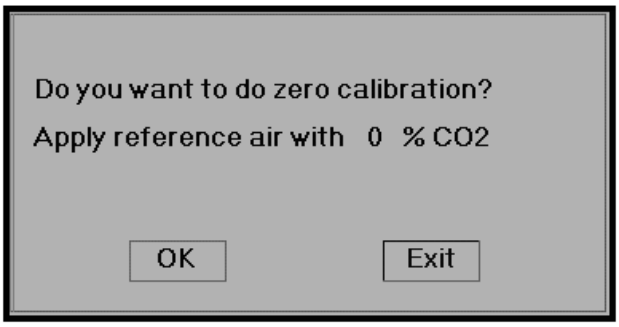
CO_2 Parameter Settings

- **Switch:** choosing the mode of CO_2. It is recommended that the switch is turned on only when there is a need to monitor CO_2 parameter. This can not only reduce the power consumption and also extend the life of the CO_2 module.

In order to maintain the monitor, please set CO_2 switch at OFF state in system setup when CO_2 function is not used.

- **Gain:** the CO_2 waveform gain.
- **Unit:** Choosing the $EtCO_2$ and the minimum $InsCO_2$. It can be set up as kPa, mmHg, and %.
- **Respiration Rate High:** Setting the upper alarm limit of CO_2 respiration rate.
  Low: Setting the lower alarm limit of CO_2 respiration rate.
- **$EtCO_2$ High:** Setting the upper alarm limit of $EtCO_2$.
  Low: Setting the lower alarm limit of $EtCO_2$.
- **$InsCO_2$ High:** Setting the upper alarm limit of $InsCO_2$.
  Low: Setting the lower alarm limit of $InsCO_2$.
- **Baro (Barometric pressure):** set ambient atmospheric pressure. It can be determined by barometer or the ambient altitude. Altitude can be used to determine the typical barometric pressure if a barometer is not available, refer to Appendix Typical Pressures and CO_2 Readings at Altitudes for details.
- **Zero:** The method to calibrate CO_2: Zero calibration. Calibration must be carried out in a drafty place, and the CO_2 module must have worked continuously for 5 minutes to ensure an accurate calibration, or the calibration will not work.
- **Flow (CO_2 flow):** It is flow rate of the CO_2 sampling. Its value is 50ml/min.

The information promoted for Zero calibration is as follows:

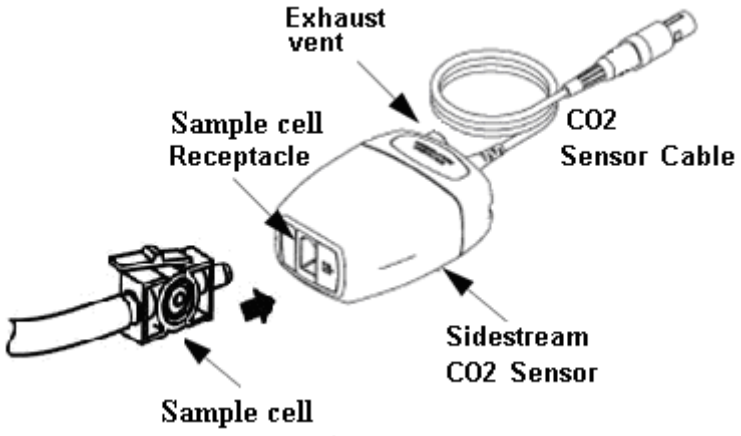


Please apply the reference air with 0% CO_2, the air in the drafty room usually can be regarded as the air with 0% CO_2. Press “OK”, and the result will be displayed on the screen several seconds later.

2. To set the color of CO_2 parameters on Color Settings screen.

5.2 CO_2 Sensor Connection

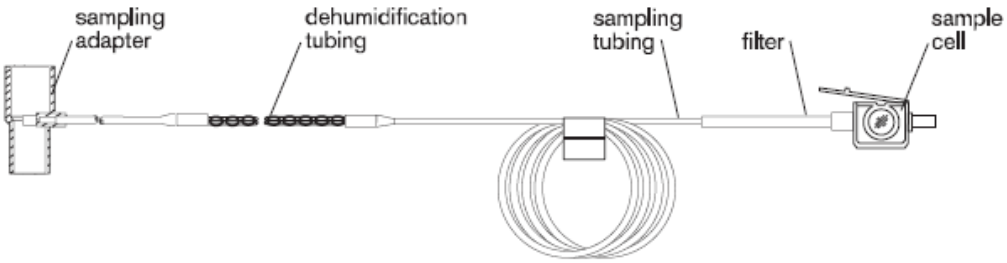
5.2.1 Sidestream CO_2 Sensor Connection



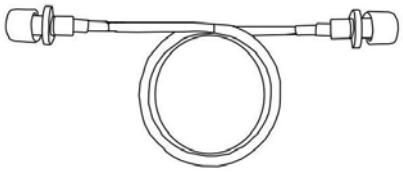
Demonstration for Sidestream CO_2 Sensor Connection

1. Take out the CO_2 Sensor and insert the CO_2 Sensor Cable into the connector labeled “CO_2” on the connector panel of the monitor;
2. The sample cell of the sampling cannula must be inserted into the sample cell receptacle of the CO_2 Sensor. A “click” will be heard when the sample cell is properly inserted. Then connect to airway tube. After finishing sensor connection, and make sure that the air input end is exposed to room air and away from all sources of CO_2, including the ventilator, the patient’s breath and your own. Next, turn on the CO_2 switch at CO_2 Setup Screen and then wait 2 minutes for the sensor warm-up.

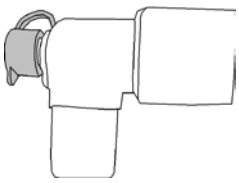
3. Default Tubing Configuration



Adapter and Sampling tube (Single patient use)



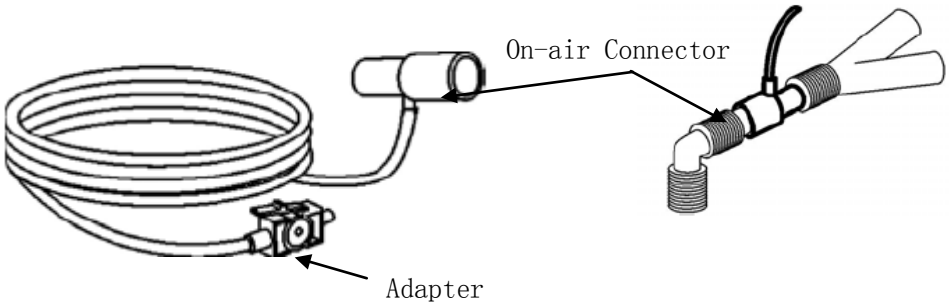
Extending airway tube for connecting to sampling tube (Single patient use)



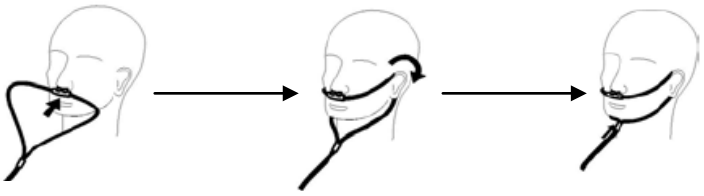
Wye Connector

4. Optional sampling cannula kits

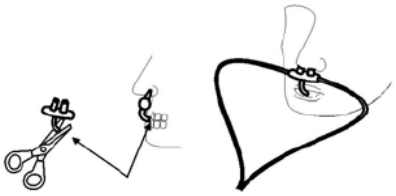
(1) T connector sampling cannula kits



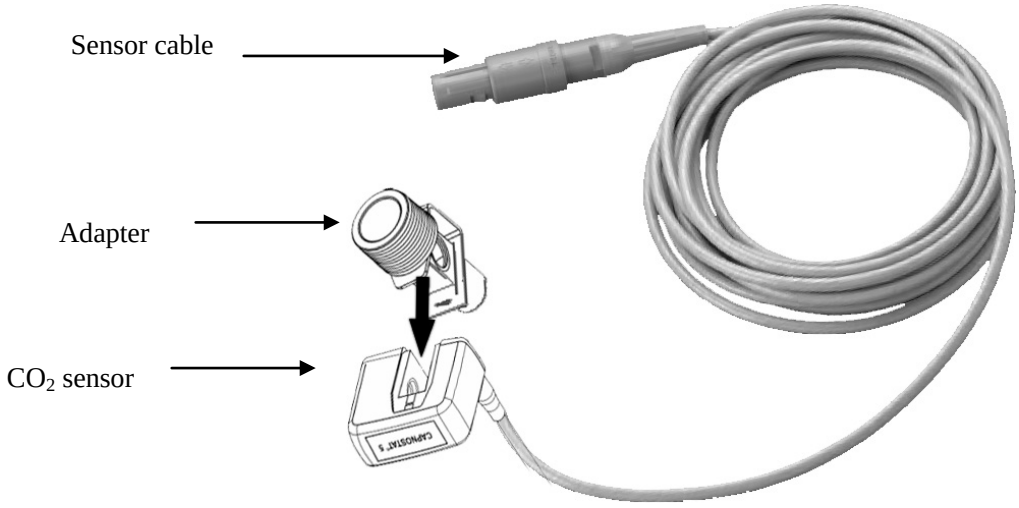
(2) Nasal Sidestream Cannula Kits



(3) Oral Sidestream Cannula Kits

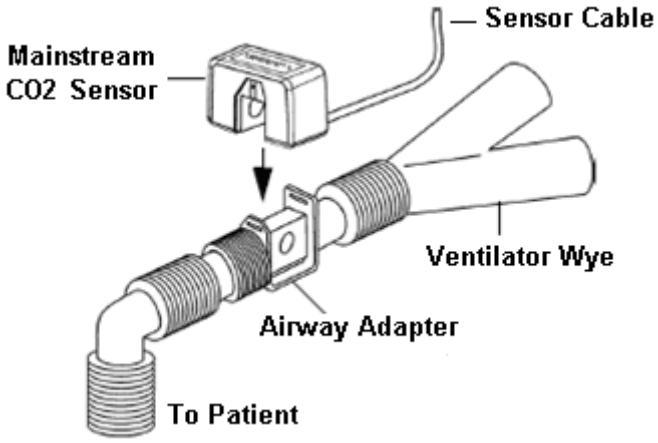


5.2.2 Mainstream CO_2 Sensor Connection



Demonstration for Mainstream CO_2 Sensor Connection

1. Take out the CO_2 Sensor and insert the CO_2 Sensor Cable into the connector labeled "CO_2" on the connector panel of the monitor;
2. Snap the CO_2 sensor onto the airway adapter as shown in Figure 6.9. A "click" will be heard when the airway adapter is properly inserted.
3. Position the airway adapter in the patient's respiratory circuit (as close to the patient as possible) between the endotracheal tube and the ventilator circuit. Next, turn on the CO_2 switch at CO_2 Setup Screen and then wait 2 minutes for the sensor warm-up.



Safety Introductions for CO_2 Monitoring

- **CO_2 Sensor is a precision measuring part, please use it correctly and store it properly;**
- **Precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.**
- **Failure of Operation: If the CO_2 Sensor fails to respond as described in this user manual; DO NOT use it until approved for use by qualified personnel.**
- **DO NOT position the sensor cables or tubing in any manner that may cause entanglement or strangulation.**
- **Support the airway adapter to prevent stress on the ET tube.**
- **Reuse, disassembly, cleaning, disinfecting or sterilizing the single patient use CO_2**

airway adapters may compromise functionality and system performance leading to a user or patient hazard. Performance is not guaranteed if an item labeled as single patient use is reused.

- **Inspect the sidestream on-airway adapters and sidestream sampling kits for damage prior to use. DO NOT use the sidestream on-airway adapters and sidestream sampling kits if they appear to be damaged or broken.**
- **If the CO_2 waveform (Capnogram) appears abnormal, inspect the CO_2 airway adapters and replace if needed.**
- **Periodically check the CO_2/Flow sensor and tubing for excessive moisture or secretion buildup. Do not use them if there is excessive moisture or exterior condensation.**
- **Electric Shock Hazard: The CO_2 Sensor contains no user serviceable parts.**
- **Refer service to qualified service personnel. Do not open the sensor cabinet at will, as electric shock hazard may occur.**
- **Place the exhaust vent of the CO_2 Sensor in drafty ambient and do not let anything block the exhaust vent.**
- **Always disconnect the CO_2 Sensor before cleaning. Do NOT use if it appears to have been damaged. Refer servicing to qualified service personnel.**
- **DO NOT sterilize or immerse the CO_2 Sensor in liquids.**
- **Replace the sidestream on-airway adapters and sidestream sampling kits if excessive secretions are observed.**
- **Do not operate the CO_2 Sensor when it is wet or has exterior condensation.**
- **Monitor the CO_2 waveform (Capnogram). If you see changes or abnormal appearance, check the patient and the sampling line. Replace line if needed.**
- **DO NOT use device on patients that can not tolerate the withdrawal of 50 ml/min +/- 10 ml/min from the airway or patients that can not tolerate the added dead space to the airway.**
- **Do not apply excessive tension to any sensor cable or pneumatic tubing.**
- **Explosion Hazard: DO NOT use in the presence of flammable anesthetics or other flammable gasses. Use of the CO_2 Sensor in such environment may present an explosion hazard.**
- **The power voltage over monitor working voltage may cause damage to CO_2 sensor. Likewise, too low power voltage may affect the CO_2 measuring accuracy or even make the CO_2 sensor not work.**
- **When changing sampling tube, it is suggested to choose the default sampling tube with dehumidifying function. The sampling tube without dehumidifying function may be easily blocked by excessive moisture. (Use life: ordinary sampling tube: 6~12 hours; the sampling tube with dehumidifying function: about 120 hours.)**
- **If the measurement appears abnormity caused by sampling tube block, please replace it.**
- **The total length of the sampling tube and extending airway tube shouldn't be longer than 3 meters, too long may cause measurement abnormity. If using T connector sampling cannula kits, please insert the sampling tube with the tubes upward to avoid the effects of excessive moisture;**
- **Altitudes are different in different area, so set the Barometric Pressure setting value as the ambient barometric pressure.**

- **Use only our company approved accessories.**
- **While using the CO_2 sensor, a system leak, which may be caused by an uncuffed endotracheal tube or a damaged CO_2 sensor may significantly affect flow-related readings. These include flow, volume, pressure and other respiratory parameters.**
- **When stopping CO_2 monitor, please disconnect the CO_2 sensor from the patient monitor.**

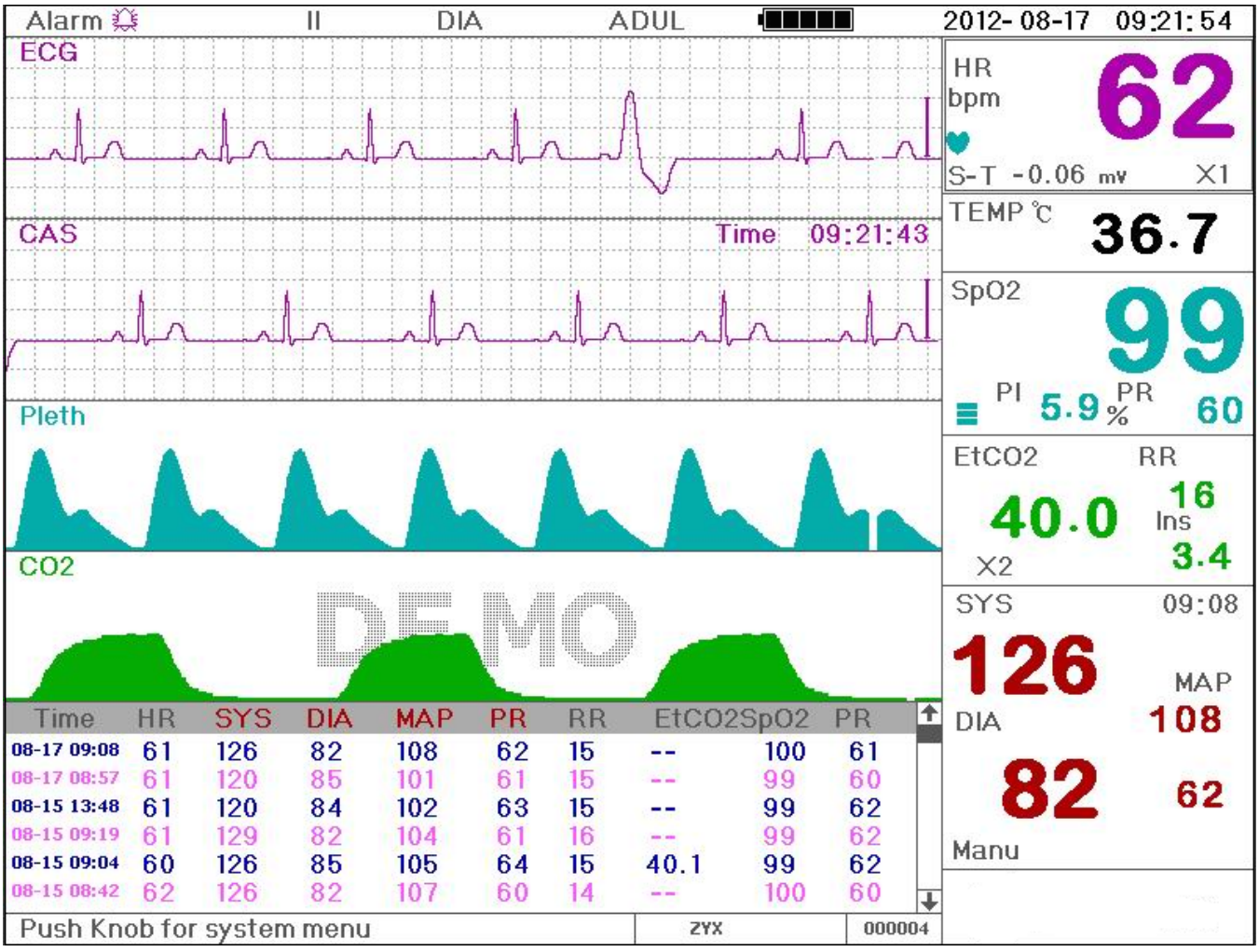
Disposal of the CO_2 Sensor and its accessories should comply with national and/or local requirements.

In the presence of electromagnetic devices (i.e., electrocautery), patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 20 V/m will not adversely affect system performance.

Nitrous oxide, elevated levels of oxygen, helium and halogenated hydrocarbons can influence the CO_2 measurement.

Excessive moisture in the CO_2 may affect the accuracy of the flow measurement.

5.3 CO_2 Monitoring Screen



Waveform area

- ✧ 5th trace: CO_2 waveform. It can be respiration waveform or CO_2 waveform.

Data area

RR, $EtCO_2$, and Ins Data Area

- ✧ **"RR":** Respiration Rate: The rpm after that is the unit of the respiration, i.e., respiration per min.
- ✧ **"$EtCO_2$ 38.1":** The label and the value will become gray when CO_2 is turned off.
- ✧ **"Ins":** The label of inhalational CO_2, the 3.0 on the lower right is the value of inhalational CO_2. The label and the value will become gray when CO_2 is turned off.
- ✧ **"16":** Respiration rate. It will display the respiration rate of CO_2, when the switch is turned on.
- ✧ **"X2":** Respiration gain（amplification）:

  "X1/2" half of the basic waveform

  "X1" basic waveform

  "X2" Twice the size of the basic waveform.

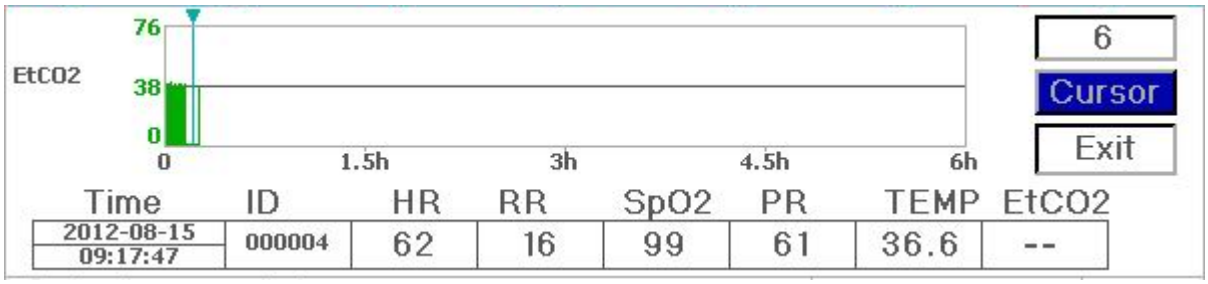
  "X4" 4 times of the basic waveform

Observing Screen, 7 Leads on the Same Screen and other display screen will display CO_2 monitoring data as well besides Main Screen.

> **Note:** only when the setting item "System Menu→SETUP→CO_2→Switch"is set as "ON", CO_2 monitoring function is available.

5.4 CO_2 Graphic Trend

On Graphic Trend screen, rotate the knob and move the cursor to "CO_2", then press the knob to enter EtCO2 Graphic Trend. Refer to Chapter 4.5 Graphic Trend Screen for detailed instructions and operations.



$EtCO_2$ Graphic Trend

Chapter 6 Alarm

6.1 Alarm Priority

High Priority:

Over HR limit
Over RR limit
Over TEMP1 limit
Over TEMP2 limit
Over SpO_2 limit
Over PR limit
Over NIBP SYS limit
Over NIBP DIA limit
Over NIBP MAP limit
Over $EtCO_2$ limit
Over $InsCO_2$ limit
Over TD limit
Over ST limit
Over NIBP PR limit
ECG VPCEST
Unable to detect HR
Unable to detect SpO_2
The battery capacity will exhaust

Medium Priority:

VE RONT
SVE RONT
Lead Off
Probe Off
Sensor Over Temp
Sensor Faulty
Zero Required
CO_2 Out of Range
Check Airway Adapter
Check Sampling Line
The Sensor Off

Low Priority:

Other arrhythmia phenomenon（Except ECG VPCEST, VE RONT and SVE RONT, refer to 12.3 Abbreviation of arrhythmia for details.）

6.2 Alarm modes

When an alarm occurs, the monitor responds with visual alarm indications (which are shown by two ways: alarm indicator and alarm message description) and audible alarm indications.

Visual Alarm Indicators

The flashing rates for the three categories of alarms are shown in the table below.

Indicator Color	**Alarm Category**	**Flashing Rate**
Red flashing	**High priority alarm**	**2 Hz**
Yellow flashing	**Medium priority alarm**	**0.5 Hz**
Yellow light	**Low priority alarm**	**Constant(on)(non-flashing)**

Audible Alarm Indications

The audible alarm has different tone pitch and on-off beep patterns for each priority category. These are summarized in the Table below.

Alarm Category	**Tone Pitch**	**Beep Rate**
High priority alarm	~500Hz	2 beeps per 7 sec.
Medium priority alarm	~700Hz	4 beeps per 9 sec.
Low priority alarm	~600Hz	20 beeps per 13 sec.
Normal	~300Hz	continuous

Note: Visual alarm indicators can not be suspended or removed. Audible alarms may be decreased in volume or silenced.

6.3 Alarm Silence

Press key to set or activate the system alarm. In the monitoring screen, press “Alarm” to set the alarm timer. There are four options of alarm silent time: 2 minutes, 5 minutes, 10 minutes and 20 minutes. The time shows up on the upper left corner of the screen. When the alarm timer is activated, the system begins to count down. If alarm occurs during that period, the system alarm will be active automatically and the monitor will give alarm. If there is no alarm during that period, when the set time has passed the system alarm will be active as well. When the monitor alarms, press key to suspend the alarm and set the alarm silence time.

DO NOT silence the audible alarm or decrease its volume if patient safety could be compromised.

6.4 Alarm Setting

In the Mode Selection screen, move the cursor to the “SETUP”, and press it to enter system setup screen.

☞ Limits setup: Move the gray cursor to the High or Low limits of the alarm settings, and press the “Alarm” key to turn ON or OFF the alarm for the setting. Yellow color shows ON status, and gray color shows the OFF status.

Refer to Chapter 11.2 for detailed Default Alarming Values of All Parameters and Setup Range.

Whenever the monitor is used, check the alarm limits to ensure that they are appropriate for the patient being monitored.

6.5 Verify Adjustable Alarm Function

To verify adjustable alarm function, select “Demo” for the item of Mode in system parameter settings menu and adjust alarm limits or change alarm setting, then pay a close attention to the alarm. If the alarm is sent out according to your setting, it means the alarm function is effective.

Chapter7 Technical Specifications

7.1 ECG Monitoring

1. Input signals range in amplitude: ± (0.5 mVp ~ 5 mVp)
2. Heart rate display range: 15 bpm ~ 350 bpm
3. Heart rate display accuracy: ± 1% or ± 1bpm, whichever is greater.
4. Alarm limits setting range: high limit: 1bpm ~350 bpm low limit: 0bpm ~ 349 bpm
5. Alarm limit setting resolution: ± 1bpm
6. Heart rate averaging:

   Average of recent eight heart beats intervals within specified range, update rate: every second.
7. Heart rate alarm delay time: ≤ 10s
8. Response time to change in heart rate:

   Change from 80 bpm to 120 bpm: < 10 sec

   Change from 80 bpm to 40 bpm: < 10 sec

   Change from 80 bpm to 0 bpm: < 10 sec
9. Tall T-wave rejection: Rejects all T-wave less than or equal to 120% of 1mV QRS.
10. Pacemaker pulse rejection:

    Rejects all pulses of amplitude ± 2mV to ± 700mV and duration 0.1 to 2 ms without overshoot.
11. Sensitivity selection:

    AUTO, Automatic scaled waveform

    ×1/4, 2.5mm/mV tolerance: ± 5%

    ×1/2, 5mm/mV tolerance: ± 5%

    ×1, 10mm/mV tolerance: ± 5%

    ×2, 20mm/mV tolerance: ± 5%

    ×4, 40mm/mV tolerance: ± 5%
12. Sweeping speed: 6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s tolerance: ±10%
13. ECG noise level: ≤ 30μV_{P-P}.
14. ECG input loop current: ≤ 0.1μA
15. Differential input impedance: ≥ 5MΩ
16. Common-mode rejection ratio (CMRR)

    Diagnostic mode: ≥ 90dB

    Operation, monitoring mode : ≥ 105dB
17. Frequency response:

    Operation mode: 1 Hz~20 Hz(+0.4dB,-3.0dB)

    Monitoring mode: 0.67 Hz~40 Hz(+0.4dB,-3.0dB)

    Diagnostic mode: 0.05 Hz~150 Hz(+0.4dB,-3.0dB)

<table>
<tr><td colspan="3">Additional declarations to conform the particular standard of IEC 60601-2-27 “Medical electrical equipment – Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment”</td></tr>
<tr><td>Direct current for respiration, leads-off sensing, and active noise suppression</td><td colspan="2">Applied current less than 0.05 microamperes.
Waveform: sine wave.
Frequency: 75 kHz</td></tr>
<tr><td>Response to irregular rhythm</td><td colspan="2">A1 Ventricular bigeminy-80BPM
A2 Slow alternating ventricular bigeminy-60BPM
A3 Rapid alternating ventricular bigeminy-120BPM
A4 Bidirectional systoles-90BPM</td></tr>
<tr><td rowspan="4">Time to ALARM for tachycardia</td><td><u>Waveform B1, Amplitude</u></td><td><u>Average Time to Alarm</u></td></tr>
<tr><td>0.5 mV
1 mV
2mV</td><td><12 sec
<12 sec
<12 sec</td></tr>
<tr><td><u>Waveform B2, Amplitude</u></td><td><u>Average Time to Alarm</u></td></tr>
<tr><td>1mV
2mV
4mV</td><td><12 sec
<12 sec
<12 sec</td></tr>
</table>

7.2 RESP Monitoring

1. RESP rate measuring range: 0rpm~120rpm
2. RESP rate accuracy: ±5% or ±2 rpm, whichever is greater
3. RESP rate alarm limits setting range: high limit: 0~120rpm; low limit: 0~119rpm
4. Alarm tolerance: ±1 rpm
5. Measuring method: Thoracic Electrical Bioimpedance

7.3 TEMP Monitoring

1. TEMP measuring range: 21.0^{o}C~50.0^{o}C
2. TEMP measuring accuracy: not greater than 0.2^{o}C for TEMP measuring range from 25.0^{o}C~45.0^{o}C
3. TEMP responding time: <150s
4. TEMP alarm limits setting range: high limit: 0.1℃ ~ 60.0℃; low limit :0℃ ~ 59.9℃
5. TEMP alarm tolerance: ±0.1℃
6. Temperature unit: ℃ (Celsius) or °F (Fahrenheit)

7.4 NIBP Monitoring

1. Measuring method: Oscillometric Technique
2. Automatic mearurement interval: 1~ 480min tolerance: <10s
3. Cuff inflation time: ≤ 10 seconds (typical adult cuff)
4. Measurement time on the average: < 90 seconds
5. Air release time while the measurement is canceled: ≤ 2 seconds (typical adult cuff)
6. Initial cuff inflation pressure

   Adult: 175 mmHg (23.3kPa) Infant: 135 mmHg (18.0 kPa)

   Neonate: 65 mmHg (8.6 kPa) Tolerance: ±5mmHg(0.67 kPa)

7. Overpressure protection limit

Adult: ≤ 300 mmHg (39.9 kPa) Infant: ≤ 240mmHg (31.9 kPa) Neonate: ≤ 150 mmHg (19.9 kPa)

8. NIBP measurement range:

Pressure（unit）		Adult	Infant	Neonate
SYS	mmHg	40~275	40~200	40~135
	kPa	5.3~36.7	5.3~26.7	5.3~18.0
MAP	mmHg	20~230	20~165	20~110
	kPa	2.7~30	2.7~22.0	2.7~14.6
DIA	mmHg	10~210	10~150	10~95
	kPa	1.3~28	1.3~20.0	1.3~12.7

9. NIBP accuracy:

Maximum mean difference: ≤ ±5 mmHg (±0.67kPa)

Maximum Standard deviation: ≤ ±8 mmHg (±1.067 kPa)

10. Measurement mode: Manual, Auto, STAT

11. NIBP alarm limits setting range:

Pressure(unit) mmHg/ kPa		Adult	Infant	Neonate
SYS	High limit	(30~280) / (4.0~37.3)	(30~200) / (4.0~26.6)	(30~135) / (4.0~18.0)
	Low limit	(29~279) / (3.8~37.2)	(29~199) / (3.8~26.5)	(29~134) / (3.8~17.8)
MAP	High limit	(21~242) / (2.8~32.2)	(21~165) / (2.8~22.0)	(21~110) / (2.8~14.6)
	Low limit	(20~241) / (2.6~32.1)	(20~164) / (2.6~21.8)	(20~109) / (2.6~14.5)
DIA	High limit	(11~232) / (1.4~30.9)	(11~150) / (1.4~20.0)	(11~100) / (1.4~13.3)
	Low limit	(10~231) / (1.3~30.8)	(10~149) / (1.3~19.8)	(10~99) / (1.3~13.2)

12. NIBP alarm tolerance: ±1.067 kPa(±8mmHg).

7.5 SpO_2 Monitoring

1. Transducer: dual-wavelength LED

Wavelength: Red light: 660 nm, Infrared light: 905 nm.

Maximal optical output power: less than 2mW maximum average

2. SpO_2 measuring range: 0%~100%

3. SpO_2 measuring accuracy: not greater than 2% for SpO_2 range from 70% to 100%

*NOTE: accuracy defined as root-mean-square value of deviation according to ISO 9919

4. Low perfusion performance: the declared accuracy is sustained when the pulse amplitude modulation ratio is as low as 0.4%.

5. SpO_2 alarm limits setting range: High limit: 1%~100% Low limit: 0%~99%

6. SpO_2 alarm tolerance: not greater than 2% for SpO_2 alarm range from 70% to 100%.

NOTE: “%” is SpO_2 percentage.

7.6 Pulse Rate Monitoring

1. Pulse rate measuring range: 0bpm~250bpm

2. Pulse rate monitoring accuracy: not greater than 2bpm for pulse rate range from 30bpm to 250bpm.

3. Pulse rate alarm limits setting range: High limit:1bpm~300bpm Low limit: 0bpm~299bpm

4. Pulse rate alarm tolerance: ±1bpm or ±1%, whichever is greater.

7.7 CO_2 Monitoring

1. Technology: Infrared absorption method.
2. Mode of Sampling: Sidestream or Mainstream
3. CO_2 Response Time:
   Sidestream: <3seconds (including transport time and rise time).
   Mainstream: <60ms (rise time)
4. Warm-up Time: Not less than two minutes
5. CO_2 measurement range: 0~150mmHg (0kPa~20kPa)
6. CO_2 Accuracy: 0~40mmHg (0kPa~5.3kPa), ±2mmHg (±0.26kPa)
   41~70mmHg (5.5kPa~9.3kPa) ±5% of reading
   71~100mmHg (9.4kPa~13.3kPa) ±8% of reading
   101~150mmHg(13.4kPa~20.0kPa) ±10% of reading

*NOTE: Gas temperature at 25°C for Sidestream;
Gas temperature at 35°C for Mainstream

7. Flow rate: 50ml/min ±10 ml/min (Sidestream)
8. CO_2 alarm limit setting range: High limit: 0.1 mmHg~150mmHg (0kPa~20kPa)
   Low limit: 0 mmHg~149.9mmHg (0kPa~19.9kPa)
9. CO_2 alarm tolerance: ±1mmHg (±0.1kPa).

7.8 Data Recording

1. Sensitivity selection tolerance: ±5%
2. Recording speed: 25mm/s
3. Recording speed accuracy: ±10%
4. Hysteresis: ≤0.5mm
5. Frequency response:
   Monitoring mode: 0.5~40Hz Diagnostic mode: 0.05~75Hz
6. Time constant:
   Monitoring mode: ≥0.3s Diagnostic mode: ≥3.2s

7.9 Other Technical Specifications

1. Electrosurgical interference suppression:
   To a certain extent, this monitor can resist against the interference from electrosurgical unit.
2. Audible alarm:
   High priority: A chain of 10 beeps with pause intervals in such way: x, x, 2x+td, x, 1s, x, x, 2x+td, x, 1s, where x (pulse interval)=100ms, td (beep duration)=160ms, 1s=1 second, the beep tone is 400Hz, the pause period between every beeping chain is 5 seconds.
   Middle priority: A chain of 3 beeps with 200ms pause interval and 200ms beep duration, the frequency is 400Hz, the pause period between every beeping chain is 5 seconds.
   Low priority: A single beep without repeat, the frequency is 500Hz, beep duration is 200ms.
3. Visible alarm:
   The visual alarm indications are represented by flashing LEDs on the upper side of monitor, parameters

display on the right area of the screen and the status line displayed on the bottom of the screen respectively. The LEDs flashing frequency and display colors are specified in the following table :

Alarm level	LED Colors	Blinking frequency	Duty rate
High priority	Red	2Hz	50%
Middle priority	Yellow	0.5Hz	50%
Low priority	Yellow	Continuous lighting	
No alarm	Green	Continuous lighting	

Parameters displayed on the screen will be inversed or flashing if corresponding alarm occurs.

4. Battery life:

Provided that a battery is new and fully charged, the minimal working time of the moniter and of its connected accessories is declared in the table below:

Monitor model	Battery life	Monitor model	Battery life	Monitor model	Battery life
PC-9000B	90min	UP-6000	90min	Deluxe-100	96min
PC-9000C	90min	UP-7000	90min	Delxue-140	100min
PC-9000S	90min	Classic-100	90min	Advance-120	90min
PC-5000A	90min	Classic-120	90min	Advance-150	95min
PC-5000B	90min	Classic-120plus	90min	PC-900/Classic-90	270min

NOTE: It will take 12-15 hours to charge battery from exhaust state to 90% charge.

5. Telemetry: Not applicable.
6. Auxiliary output: Not applicable.
7. Alarm Silencing: There are four options of alarm silent time: 2 minutes, 5 minutes, 10 minutes and 20 minutes. It takes 1 second to restart the alarm after the silencing alarm is disabled.
8. Parts with protection against the discharge of defibrillator: NIBP cuff, SpO_2 probe and built-in ECG module.
9. The NIBP measuring technique of this monitor is equivalent to the stethoscope method. The measurement tolerance is complied with the standard ANSI/AAMI SP10:1992.
10. The monitor is applicable to connect to the public mains power network.
11. Power supply voltage: 100~240VAC, frequency: 50/60Hz
12. Input power consumption: <100VA (for PC-900 and Classic-90: <50 VA)
13. Display screen: true color TFL LCD panel.
14. Alarming forms: audible & visible alarm
15. Communication network: Ethernet

7.10 Classification

Safety standard:	IEC 60601-1
The type of protection against electric shock:	Class I equipment
The degree of protection against electric shock:	With Type BF,CF applied parts
Electro-Magnetic Compatibility:	Group I, Class A
The type of resistance against electric shock:	Class I with internal power supply
Operation mode	Continuous
The degree of protection from harmful liquid	Ordinary device without water-proof capability
Sterilization and disinfection methods	Sterilization and disinfection methods recommended by manufacturer

7.11 Guidance and manufacturer's declaration-Electromagnetic compatibility

Table 1

Guidance and manufacturer's declaration-electromagnetic emission-for all EQUIPMENT AND SYSTEMS

<table>
<tr><td colspan="3">PC-5000 Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment-guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>PC-5000 Patient Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">PC-5000 Patient Monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions
IEC61000-3-3</td><td>Complies</td></tr>
</table>

Table 2

Guidance and manufacturer's declaration-electromagnetic immunity for all EQUIPMENT AND SYSTEMS

PC-5000 Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment or system should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Electrostatic discharge(ESD) **IEC61000-4-2**	±6 kV contact ±8kV air	±6 kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. if floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst **IEC61000-4-4**	±2kV for power Supply lines ±1 kV for input/output lines	±2kV for power Supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge **IEC 61000-4-5**	±1kV line (s) to line(s) ±2kV line(s) to earth	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines **IEC61000-4-11**	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment or system requires continued operation during power mains interruptions, it is recommended that the equipment or system be powered from an uninterruptible power supply or a battery.
Power frequency(50Hz/60Hz) magnetic field **IEC61000-4-8**	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity-for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

PC-5000 Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of PC-5000 Patient Monitor should assure that it is used in such an electromagnetic environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of PC-5000 Patient Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ,[a] should be less than the compliance level in each frequency range .[b] Interference may occur in the vicinity of equipment marked with the following symbol.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which PC-5000 Patient Monitor is used exceeds the applicable RF compliance level above, PC-5000 Patient Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating PC-5000 Patient Monitor.

b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the equipment or system- for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

PC-5000 Patient Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment or system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment or system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	80MHz to 2,5GHz $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Chapter 8 Packaging and Accessories

8.1 Packaging

The product is packed in high quality corrugated cartons with foam inside to protect the equipment against damage in the shipping and handling process.

Gross Weight: see the packaging
Dimensions: 500mm x 320mm x 460mm

8.2 Accessories

(1) ECG lead cable — One set
(2) NIBP cuff — One set
(3) SpO_2 probe — One piece
(4) Body surface temperature probe — One piece
(5) Power cable — One piece
(6) Grounding wire — One piece
(7) Disposable electrode — Ten pieces
(8) User Manual — One copy
(9) Warranty — One copy
(10) Printing paper (optional) — Five rolls
(11) Dust cover — One set
(12) Assembly report — One set
(13) Packing list — One piece
(14) CO_2 accessories (optional)

For Mainstream		**For Sidestream**	
Mainstream sensor (CAPNOSTAT 5)	One set	Sidestream Sensor (LoFlo C5)	One set
Airway adapter	One piece	Sampling Line Kit	One set

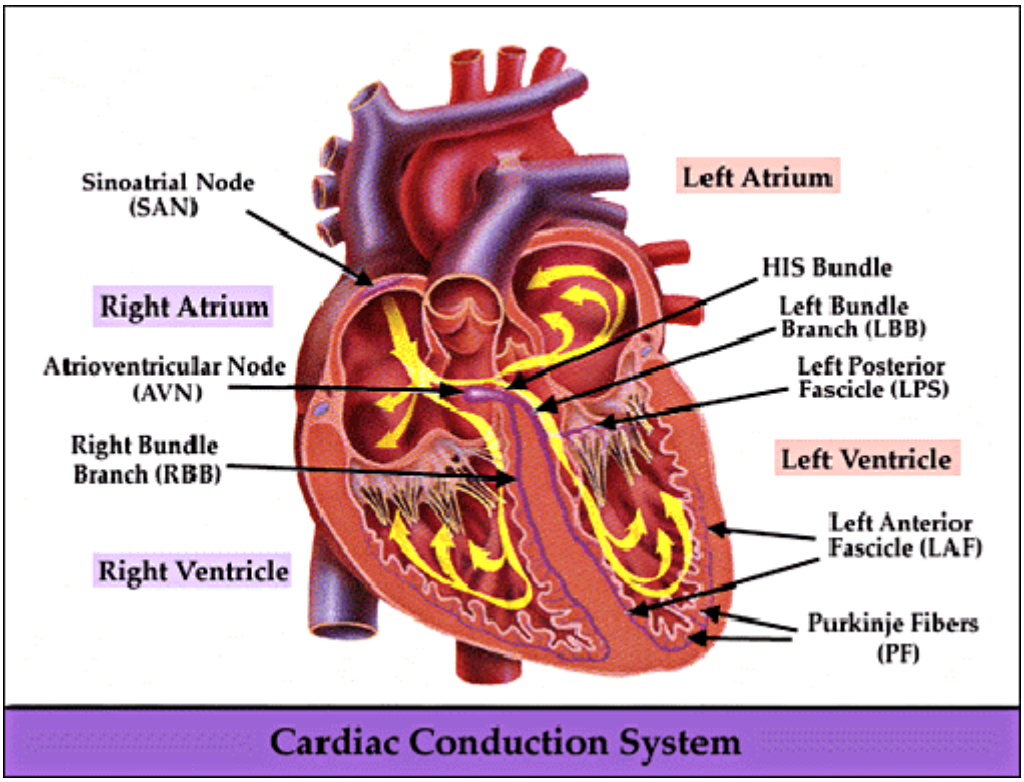
Note: The accessories are subject to change. Detailed items and quantity see the Packing List.

Chapter 9 Parameters Monitoring

9.1 ECG Monitoring

9.1.1 How to Obtain High Quality ECG and Accurate Heart Rate Value

The electrocardiogram (ECG or EKG) is primarily a tool for evaluating the electrical events within the heart. The action potentials of cardiac-muscle cells can be viewed as batteries that cause charge to move throughout the body fluids. These currents represent the sum of the action potentials occurring simultaneously in many individual cells and can be detected by recording electrodes at the surface of the skin. The figure below shows the system of the heart.



First of all, the hospital should be equipped with a 100~250V power supply system with a typical grounding wire. If big interference in ECG continues, connect one end of the grounding wire provided with this equipment to the grounding wire on the back panel of this monitor, and the other end to the special grounding wire, water pipe or radiator.

A common ECG plate electrode used together with this monitor has short shelf life. Generally, the shelf life is only one month after the package is opened. When outdated plate electrode is used, due to skin's contact impedance and big electrode potential, the chance of interference will be increased, and the ECG baseline will have an unstable inclination. Therefore, always use valid plate electrodes.

9.1.2 Factors affecting ECG signal

- ✧ Interference from Electrosurgical Unit;
- ✧ Doesn't filter the interference waveform;
- ✧ Poor grounding;
- ✧ Electrodes are not placed properly;
- ✧ Use expired electrode or use disposable electrode repeatly;
- ✧ The skin placed electrode is unclean or poor contract caused by scurf and hair;
- ✧ Electrode long-time used.

9.2 NIBP Monitoring

9.2.1 Measuring Principle

Blood pressure may be measured in an invasive way (whereby the sensor will be inserted into blood vessel directly) or a non-invasive way. The non-invasive way includes several methodologies, such as the Korotkoff Sound Method and oscillating method. The Korotkoff Sound Method is used as a conventional way, whereby stethoscope is used to measure the blood pressure. By the oscillating method, an inflation pump will fill the air, and release it slowly. A computer will record change of the cuff pressure when the air is released. With this record, the blood pressure value will be determined. First of all, make sure the signal quality judgment by computer meets the requirements of accurate calculation (such as sudden limb movement or cuff being hit during the measurement). If the answer is negative, give up the calculation. If the answer is positive, proceed with calculation of the blood pressure value.

As change of the blood pressure is recorded by electric sensor, which sensitivity is much higher than that of human ears, the oscillating method uses different definitions for measurement of diastolic pressure, mean arterial pressure and systolic pressure from the Korotkoff Sound Method. When the oscillating method is used, the circuit in the measuring apparatus will separate the amplitude of the cuff pressure from its change with pulsation. With the oscillating method, the blood pressure at the maximum amplitude of cuff pressure is defined as the mean arterial pressure. The blood pressure at amplitude of cuff pressure forward reduced according to proper proportion is defined as systolic pressure, while the blood pressure at amplitude of cuff pressure backward reduced according to proper proportion is defined as diastolic pressure. The maximum change of pulse pressure occurs at these two points. They are equivalent to the point with pulse sound and the point without pulse sound respectively in the Korotkoff Sound Method.

When the risk of invasive monitoring method outweighs its advantage of accuracy, non-invasive monitoring method shall be used.

Comparison between blood pressure measuring methods

To overcome the effect of human hearing variation and air release speed on measurement accuracy when the conventional Korotkoff Sound Method is used to take measure of blood pressure, people have been dedicated to study of automatic measurement of blood pressure. By now, automatic blood pressure measuring system based on the principle of oscillating method is mature. In practice, however, various problems are encountered, such as why the measures taken by the oscillating method is lower or higher than those taken by Korotkoff Sound Method? Why the measures are inclined to decline? Why, in some cases, no result is obtained in spite of the inflation actions? Why the measure values have big discreteness and even abnormal data in some cases? Why the SpO_2 waveforms may disappear suddenly? ...and so on. The following explanations are devised to give the answers.

The Oscillating method vs. the Korotkoff Sound Method

Blood pressure measurement by the oscillating method and Korotkoff Sound Method has good correlation with the invasive measurement. Notwithstanding, any of the non-invasive blood pressure measurements has its one-sidedness when it is compared to the invasive measurement. The oscillating method has its advantages over the Korotkoff Sound Method in less error, higher reliability and stability. Their differences may be reflected in the following aspects.

1. The measures by the Korotkoff Sound Method are liable to effect of human factors. For example, different people may have different sound judging ability, or different reactivity when listening to heart sound and reading mercury meter. The air release speed and subjectivity may also affect the judgment. By the oscillating method, the computation is accomplished by the computer, thus relieving the possibility of effect due to human factor.
2. With the Korotkoff Sound Method, the measure is taken on the basis of appearance and disappearance of heart sound. The air release speed and heart rate may have direct effect on the measurement accuracy. It also has the

disadvantages of rapid air release and poor accuracy. In the contrast, with the oscillating method, the determination is calculated on the basis of cuff pressure oscillatory waveform envelope, and the air release speed and heart rate has little effect on the measurement accuracy.

3. Statistics show that, when measuring the hypertension, the measure taken by the oscillating method is likely to be lower than that taken by the Korotkoff Sound Method. When measuring the hypotension, the measure taken by the oscillating method is likely to be higher than that by the Korotkoff Sound Method. But, it doesn't mean the advantages or disadvantages between the oscillating method and the Korotkoff Sound Method. Comparison with the results taken by more accurate method, let's say comparison of the invasive pressure result with the output value by the blood pressure measuring simulator, will show which method has more accurate results. In addition, higher or lower value should be a statistical concept. It is recommended those used to adopt the Korotkoff Sound Method use different physiological calibration for values determined by the oscillating method.
4. The studies have shown that the Korotkoff Sound Method has the worst accuracy when it comes to measurement of hypotension, while the oscillating method has worse accuracy when it comes to measurement of controlled hypertension relief.

9.2.2 Factors affecting NIBP measuring

Like common non-invasive blood pressure measurement, improper operation may cause inaccurate or blank result or misunderstanding of the measuring information when the oscillating method is used to take the measure of blood pressure. This point needs particular attention of the operators.

1. Requirements of the cuff:
   1) Appropriate cuff should be selected according to the age of the subject. For more information, see Chapter 3.
   2) Remember to empty the residual air in the cuff before the measurement is commenced.
   3) Locate the cuff in such a way that the "φ" mark is at a location where the clearest pulsation of brachial artery is observed.
   4) The cuff should be tightened to a degree where insertion of one finger is allowed.
   5) The lower end of the cuff should be 2cm above the elbow joint.
2. The subject should lie on the back so that the cuff and the heart are in a horizontal position and the most accurate measure is taken. Other postures may lead to inaccurate measurement.
3. Do not speak or move before or during the measurement. Care should be taken so that the cuff will not be hit or touched by other objects.
4. The measures should be taken at appropriate intervals. Continuous measurement at too short intervals may lead to pressed arm, reduced blood flow and lower blood pressure, and resulting inaccurate measure of blood pressure. It is recommended the measure be taken at intervals of more than two minutes.
5. With the oscillating method, when blood pressure is measured, the inflation pressure of the cuff will be automatically adjusted according to the previous measure. Generally, the initial inflation pressure is 180mmHg (for the adult mode) or 100mmHg (for the infant mode) or 80 mmHg (for the neonate mode) when it is powered on. Following that, 50mmHg (for the adult mode) or 30mmHg (for infant mode) or 10mmHg (for the neonate mode) will be added on the basis of the last measurement of systolic pressure. In this way, when the blood pressure rises or the subject is changed, the blood pressure meter may fail in giving the result after the first-time inflation. This monitor will automatically adjust the inflation pressure until the measure is taken, after that, up to four measures will be allowed.
6. When an adult subject is monitored, the machine may fail in giving the blood pressure measure if the infant or neonate mode is selected.

9.2.3 Clinical Limitations

1. Serious angiospasm, vasoconstriction, or too weak pulse.
2. When extremely low or high heart rate or serious arrhythmia of the subject occurs. Especially auricular fibrillation will lead to unreliable or impossible measurement.
3. Do not take the measurement when the subject is connected with an artificial heart-lung machine.
4. Do not take the measurement when the subject uses diuresis or vasodilator.
5. When the subject is suffering from major hemorrhage, hypovolemic shock and other conditions with rapid blood pressure change or when the subject has too low body temperature, the reading will not be reliable, for reduced peripheral blood flow will lead to reduced arterial pulsation.
6. Subject with hyperadiposis;

In addition, statistics show that 37% people report blood pressure difference of no less than 0.80kPa(6mmHg) between the left and right arms, and 13% people report difference of no less than 1.47kPa (11mmHg).

Note: Some practitioners may report big discreteness or abnormal value of the blood pressure measures when the oscillating method is used. As a matter of fact, the so-called "big discreteness" must be a term in the sense of statistical significance of mass data. Abnormal data may be observed in some individual cases. It is normal in the scientific experiments. It may be caused by an apparent reason, or by an unknown factor in some cases. Such individual doubtful experimental data may be identified and eliminated using the special statistical technique. It is not a part of this manual. The practitioner may eliminate the apparently unreasonable data according to the experience.

Operation Introduction:

1. Take a measurement in manual mode:
   - ◆ Enter into the screen of NIBP setting, select "Mode" option and set it as "MANU", and then press the NIBP key on the front panel to start measure. If press the NIBP key again, the measurement will be stopped.
   - ◆ During the automatic measurement interval when no NIBP measurement is taken, press the NIBP key, a measurement in manual mode will be taken. If at this time press the NIBP key again, the manual mode will be stopped and continue the automatic mode.
2. Take a measurement in automatic mode:

   Enter into the screen of NIBP setting, select "Cycle" option and select time interval according needs, then press the NIBP key on the front panel to start the automatic measurement at a certain interval.
3. Stop automatic measurement

   In the procedure of automatic measurement, press the NIBP key at any time, the measurement will be stopped.
4. STAT measurement

   Enter into the screen of NIBP settings, select Cycle option and set as STAT, the STAT measurement will be taken. This procedure will last for 5 minutes.
5. Stop STAT measurement on the halfway

   In the procedure of STAT measurement, press the NIBP key at any time, the measurement will be stopped.

9.3 SpO_2 Monitoring

9.3.1 Measuring Principle

Based on Lamber-Beer law, the light absorbance of a given substance is directly proportional with its density or concentration. When the light with certain wavelength emits on human tissue, the measured intensity of light after absorption, reflecting and attenuation in tissue can reflect the structure character of the tissue by which the light passes. Due to that oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light (600nm~1000nm wavelength), by using these characteristics, SpO_2 can be determined. SpO_2 measured by this monitor is the functional oxygen saturation -- a percentage of the hemoglobin that can transport oxygen. In contrast, hemoximeters report fractional oxygen saturation – a percentage of all measured hemoglobin, including dysfunctional hemoglobin, such as carboxyhemoglobin or metahemoglobin.

9.3.2 SpO_2 Measurement Restrictions (interference reason)

1. The fingers should be properly placed (see the attached illustration of this instruction manual), or else it may cause inaccurate measurement result.
2. Make sure that capillary arterial vessel beneath the finger is penetrated through by red and infrared lights.
3. The SpO_2 sensor should not be used at a location or limb tied with arterial or blood pressure cuff or receiving intravenous injection.
4. Do not fix the SpO_2 sensor with adhesive tape, or else it may result in venous pulsation and consequential inaccurate measurement result of SpO_2.
5. Make sure the optical path is free from any optical obstacles like adhesive tape.
6. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, and direct sunlight etc.
7. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
8. Please do not use the SpO_2 sensor when having the MRI, or burn may be caused by faradism.
9. Always observe the plethysmogram (waveform), which is auto-scaled within the range of 100. The SpO_2 reading may be unlikely true when the waveform is not smooth or irregular. If in doubt, rely on your clinical judgment, rather than the monitor readout
10. A functional tester can not be used to assess the accuracy of the pulse oximeter monitor or a SpO_2 sensor. However, a functional tester, such as SpO_2 simulator can be used to check how accurately a particular pulse oximeter is reproducing the given calibration curve. Before testing the oximeter by a functional tester, please firstly ask the manufacturer which calibration curve is used, if necessary, request the manufacturer for its dedicated calibration curve and download it into the tester.

Clinical Limit

1. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood stream of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
2. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 determination by this monitor may be inaccurate.
3. The drugs such as dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO_2 measurements.
4. As the SpO_2 value serves as a reference value for judgment of anemic anoxia and toxic anoxia, the measurement result of some patients with serious anemia may also present as good SpO_2 value.

9.4 Respiration Monitoring

9.4.1 Measuring Principle

The air will be filled into alveolus or be expelled during respiration, and the chest's volume changes with this process. Because the conductivity of air is lower than body tissues, the chest's impedance will be changed by the inflation. With this specialization, the respiration can be monitored through putting safe current into body and measuring the change of voltage between the electrodes. The product will transmit the high-frequency current whose frequency is much higher than ECG frequency (but with the safe current limit) to the ECG electrodes (placed at the both sides of chest), which can be detect ECG signal and chest's impedance at the same time, and the respiratory rate will be measured through impedance method by the software. So the additional electrodes for respiratory measurement are unnecessary.

9.4.2 Factors affecting respiration monitoring

- ✧ Place the white (RA) and red (LL) electrodes on the cross, if the line between two electrodes in liver area or heart area, the artificial error may occur.
- ✧ Respiration monitoring doesn't support monitoring the patient who do much movement, or may lead to wrong alarm.

9.5 Temperature Monitoring

The sensor is thermo-resistor type (25 ℃ 5kΩ)
the temperature of measured part through measuring the voltage. There is a period responding time, so the accurate temperature value display after a while. The temperature monitoring can be divided into two measuring method: measure through body surface temperature and through the temperature inside the body cavity (placed in mouth or anus).

Normal value: body surface: 36.5 ℃~37℃; inside body cavity: 36.5℃~

Notes:

- ➢ Attach the TEMP transducer to the patient; generally if the TEMP transducer and skin doesn't contact closely, the measured value becomes lower, so for those who have requirement for temperature, add a proper martial to transducer and fix it with adhesive tape to make them contact firmly.
- ➢ Especially for pediatric patient, they like sports, pay more attention to the transducer fixing.

9.6 CO_2 Monitoring

9.6.1 Measuring Principle

The principle is based on the fact that CO_2 molecules absorb infrared light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration. When an IR light beam is passed through a gas sample containing CO_2, the electronic signal from a photodetector (which measures the remaining light energy), can be obtained. This signal is then compared to the energy of the IR source, and calibrated to accurately reflect CO_2 concentration in the sample. To calibrated, the photodetector's response to a known concentration of CO_2 is stored in the monitor's memory.

The monitor determines CO_2 concentration in the breathing gases by measuring the amount of light absorbed by these gases.EtCO_2 is display as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, a CO_2 waveform (capnogram) may be displayed which is a valuable clinical tool that can be used to assess patient airway integrity and proper endotracheal tube placement. Respiration rate is calculated by measuring the time interval between detected breaths.

9.6.2 Mainstream vs. Sidestream Sampling

Mainstream CO_2 sensors are placed at the airway of an intubated patient, allowing the inspired and expired gas to pass directly across the IR light path. The major advantages of mainstream sensors are fast response time and elimination of water traps.

Sidestream CO_2 sensors are located away from the airway, requiring a gas sample to be continuously aspirated from the breathing circuit and transported to the sensor by means of a pump. This type of system is needed for non-intubated patients.

When using mainstream CO_2 sensors, check the window for the patient secretions pooled on periodically. Because that condition may affect the accuracy of the measurement or even make the sensor not work.

When using sidestream CO_2 sensors, there is a water trap or a part of the sampling tube with dehumidifying function. Please periodically check the flow sensor and tubing for excessive moisture or secretion buildup.

Chapter 10 Troubleshooting

Note: To troubleshoot this machine in the service, follow the instructions below to eliminate the problem first. If the attempt fails, refer to the dealer in your local area or the manufacturer. The service should be performed by a professional electrician. Do not open the machine by yourself.

10.1 No Display on the Screen

1. Shut down the machine and unplug the power. Use a universal multi-meter to check if the outlet has proper voltage, if the power cable is in good condition, and if the power cable is properly connected with this apparatus or the outlet? Remove the fuse from the back cover of this machine, and make sure it is in good condition.
2. If the trouble still exists, loosen the screws fastening the top cover of the machine and open the top cover. Check if the signal plug of the monitor is properly connected with the Type D jack on the right side of the display card

10.2 Excessive ECG Signal Interference or Thick Baseline

1. Check if the plate electrodes are properly located, and if valid plate electrodes are used.
2. Are the lead wires properly inserted? If no ECG curve is displayed, check if the ECG lead wires are broken.
3. Does the mains outlet have standard grounding wire?
4. Is the exclusive grounding wire of the apparatus properly grounded?

10.3 No Blood Pressure and Pulse Oxygen Measurements

1. Check if the blood pressure cuff is properly wrapped around the arm according to the operating instructions, if the cuff leaks, and if the inlet is closely connected with the NIBP jack on the front panel? Check if the indicator of the pulse oxygen probe flashes and if the pulse oxygen probe is properly connected to the SpO2 jack on the front panel.
2. Loosen the four screws fastening the top cover of this apparatus and check if the multifunctional board (MID) and electronic disc card (SCPU) nearest to the rear end of the LCD display are properly inserted in the slots on the main board.

10.4 System Alarm

1. When the parameter value is higher or lower than the alarm limits, the alarm will ring. Please check whether the alarm limit value is proper or the condition of the patient.
2. Leads off. Please check the connection of the leads.
3. Probe off. Please check the connection of the probes.

Chapter 11 Maintenance

The patient monitor should be properly maintained to ensure its maximum performance and long service life. In addition to the warranty period of one year, the company also offers long-term service for each customer. It is important that the users read and follow the operating instructions, important information and maintenance measures.

11.1 Protective Maintenances

Before using the monitor, the checks below should be carried out:

- Check the monitor for any mechanical damage;
- Inspect the exposed parts and the inserted parts of all the leads, and the accessories;
- Examine all the functions of the monitor that are likely to be used for patient monitoring, and ensure that it is in good working condition;
- Make sure that the monitor is grounded properly.
- Pay close attention to the fluctuation of the local power supply voltage. A manostat is recommended when necessary.

In case any indication of damage about the function of the monitor is detected and proven, it is not allowed to apply it to the patient for any monitoring. Please contact the local dealer or our company, and we are to offer the best solution as soon as possible for your satisfaction.

After each maintenance or the yearly maintenance, the monitor must be thoroughly inspected by qualified professional, including function and safety examinations. The designed life of this monitor is 5 years. In order to ensure its long service life, please pay attention to the maintenance.

- **If the hospital fails to carry out a satisfactory maintenance program about the monitor, it may get disabled and harm the patient's safety and health.**
- **In case of ECG leads damage or aging, please replace the lead.**
- **If there is any indication of cable and transducer damage or they deteriorate, they are prohibited from any further use.**
- **The adjustable units in the monitor such as potentiometer are not allowed to adjust without permission to avoid unnecessary failures that affect normal application.**
- **It is recommended to use the battery once a month to ensure its strong power supply capacity and long service life, and recharge it after run out of the power volume.**

11.2 Battery Maintenance

- **Please pay attention to the polarity of battery, do NOT insert it into battery compartment with reversed polarities;**
- **Do NOT use the batteries manufactured by other companies, if being inserted, the device may be damaged;**
- **In order to avoid damaging the battery, do NOT use other power supply device to charge the battery;**
- **After battery ageing phenomenon occurring, do NOT throw the battery into fire to avoid explosion risk.**
- **Do not hit or strike it with force;**
- **Do not use this battery on other devices;**

- **Do not use this battery below -10℃ or above 40℃;**
- **Abandoning battery should obey the local law.**
- **In order to maintain battery supply time and prolong battery lifetime, please charge the battery every one or two months if don't use battery for a long time. And do charge battery at least 12-15 hours every time. Before connect to AC, do start monitor with battery's power supply, until battery power is used up and monitor turn off automatically, then connect monitor to AC and have it charged for 12-15 hours continuously. The speed of charge will be the same no matter whether the monitor is working or not. The reason why discharge the battery before charge is to avoid the decrease of capacity caused by battery's memory effect. If the monitor won't be used for a long time, do have it charged fully before conservation.**
- **When starting the monitor by battery power only which is short of supply, monitor will turn off automatically. In order to avoid the damage to battery caused by excessive discharge, please pay attention to following. After monitor turns off automatically, there is still small drain current inside battery, so it is suggested that user should press the power button again to cut off the power supply. If battery keeps in a state of small drain current, battery will be damaged and can't be repaired because of excessive discharged.**
- **If battery is damaged, please replace with same type and specification battery marked by "CCC" or "CE" in time, or contact the company directly.**

11.3 Cleaning, Sterilization and Disinfection of the Monitor

- **Switch off the monitor and disconnect the power cable before cleansing.**
- Kept the monitor from dust.
- It is recommended to clean the outer shell and screen of the monitor to keep it clean. Only non-corrosive cleanser such as clear water is permitted.
- Wipe the surface of the monitor and transducers with an alcohol impregnated wipe, and dry it with dry and clean wipe or simply air-dry.
- It is advisable to disinfect and sterilize the apparatus when necessary in the hospital maintenance program to avoid causing long term damage to the monitor, and to clear the sterilizing and disinfecting tools in advance.
- **Do not let the liquid cleanser flow into the connector jack of the monitor to avoid damage.**
- **Clean the exterior of the connector only.**
- **Dilute the cleanser.**
- **Do not use scrub materials.**
- **Do not let any liquid flow into the shell or any parts of the monitor.**
- **Do not let the cleanser and disinfectant stay on its surface.**
- **Do not perform high pressure sterilization to the monitor.**
- **Do not put any parts of the monitor or its accessories in the liquid.**
- **Do not pour the disinfector on its surface while sterilization.**
- **If the monitor is accidentally wetted it should be thoroughly dried before use. The rear cover can be removed by qualified service technician to verify absence of water.**
- **Never use this machine in an environment with inflammable gas.**
- **Avoid being hit by lightning. The power cable should be plugged into an outlet with grounding wire. Do not use an outlet with poor condition. If possible, use power supply system with manostat.**
- **It must be used in a clean environment protected against shock. Keep it away from corrosive substances, explosive substances, high temperature and dampness.**
- **If it is installed in a cabinet, make sure the installation allows for good ventilation, and easy to maintain, observe and operate.**

11.4 Cleaning, Sterilization and Disinfection of Accessories

It is recommended to clean the accessories (including sensor, leads and plugs) with a piece of gauze which has been soaked in 75% Alcohol or 70% Ispropanol before use.

- **Do not use damaged accessories.**
- **Accessories can not be entirely immerged into water, liquor or cleanser.**
- **Do not use radial, steam or epoxyethane to disinfect accessories.**

11.5 Storage

If the apparatus will not be used for long period of time, wipe it clean and keep it in the package, which shall be kept in a dry place free from dust.

Storage environment:	ambient temperature:	-20℃~60℃
	relative humidity:	10%~90%
	atmospheric pressure:	53kPa~106kPa

11.6 Transportation

This monitor should be transported by land (vehicle or railway) or air in accordance with the contractual terms. Do not hit or drop it with force.

Chapter 12 Appendix

12.1 Alarm Information

Alarm Information	Descriptions
Over HR limit	The related parameter value exceeds the preset high/low alarm limit.
Over RR limit	
Over TEMP limit	
Over SpO_2 limit	
Over PR limit	
Over NIBP SYS limit	
Over NIBP DIA limit	
Over NIBP MAP limit	
Over ST limit	
Over NIBP PR limit	
Unable to detect HR	ECG cable and leads are connected to monitor and patient well, but HR is unable to be detected. It may caused by inconformity HR signal.
Unable to detect SpO_2	SpO_2 probe is connected to monitor and patient well, but SpO_2 is unable to be detected. It may be caused by inconformity SpO_2 signal.
The battery capacity will exhaust	Low battery voltage
Lead Off	The ECG electrodes or cable fell off
Probe Off	SpO_2 probe fell off

12.2 Default Alarming Values and Setup Range

The default alarming value:

Parameter \ Mode			Adult	Infant	Neonate
Heart Rate		High limit	180 bpm	200 bpm	220 bpm
		Low limit	40 bpm	50 bpm	50 bpm
Respiration		High limit	40 rpm	50 rpm	60 rpm
		Low limit	10 rpm	10 rpm	10 rpm
Temperature		High limit	39℃	39℃	39℃
		Low limit	35℃	35℃	35 ℃
NIBP	Systolic	High limit	180 mmHg	130 mmHg	110 mmHg
		Low limit	60 mmHg	50 mmHg	50 mmHg
	Diastolic	High limit	120 mmHg	90 mmHg	90 mmHg
		Low limit	50 mmHg	40 mmHg	30 mmHg
	MAP	High limit	160 mmHg	110 mmHg	100 mmHg
		Low limit	50 mmHg	40 mmHg	30 mmHg
SpO_2		High limit	100%	100%	100%
		Low limit	90%	85%	85%
Pulse Rate		High limit	180 bpm	200 bpm	220 bpm
		Low limit	40 bpm	50 bpm	50 bpm
ST Segment		High Limit	+1.00mV	+1.00mV	+1.00mV
		Low Limit	-1.00mV	-1.00mV	-1.00mV
Temperature Difference		Range	2℃	2 ℃	2 ℃
Arterial Pressure	SYS	High limit	200mmHg	160mmHg	140mmHg
		Low limit	10mmHg	10mmHg	10mmHg
	DIA	High limit	200mmHg	160mmHg	140mmHg
		Low limit	10mmHg	10mmHg	10mmHg
	MAP	High limit	200mmHg	160mmHg	140mmHg
		Low limit	10mmHg	10mmHg	10mmHg
Pulmonary Artery Pressure	SYS	High limit	120mmHg	100mmHg	90mmHg
		Low limit	10mmHg	10mmHg	10mmHg
	DIA	High limit	120mmHg	100mmHg	90mmHg
		Low limit	10mmHg	10mmHg	10mmHg
	MAP	High limit	120mmHg	100mmHg	90mmHg
		Low limit	10mmHg	10mmHg	10mmHg
Central Venous Pressure	SYS	High limit	30mmHg	30mmHg	30mmHg
		Low limit	0mmHg	0mmHg	0mmHg
	DIA	High limit	30mmHg	30mmHg	30mmHg
		Low limit	0mmHg	0mmHg	0mmHg
	MAP	High limit	30mmHg	30mmHg	30mmHg
		Low limit	0mmHg	0mmHg	0mmHg
CO_2	Respiration Rate	High limit	40 rpm	50 rpm	60 rpm
		Low limit	10 rpm	10 rpm	10 rpm
	$EtCO_2$	High limit	70 mmHg	70 mmHg	70 mmHg
		Low limit	10 mmHg	10 mmHg	10 mmHg
	$InsCO_2$	High limit	10 mmHg	10 mmHg	10 mmHg
		Low limit	0 mmHg	0 mmHg	0 mmHg

The high and low limits setting range:

Parameter \ Mode			Adult	Infant	Neonate
Heart Rate		High limit	1~350bpm	1~350bpm	1~350bpm
		Low limit	0~349bpm	0~349bpm	0~349bpm
Respiration		High limit	1~120rpm	1~150rpm	1~150rpm
		Low limit	0~119rpm	0~149rpm	0~149rpm
Temperature		High limit	0.1~60℃	0.1~60℃	0.1~60℃
		Low limit	0~59. 9℃	0~59. 9℃	0~59. 9℃
Systolic		High limit	30~280 mmHg	30~200 mmHg	30~135 mmHg
		Low limit	29~279 mmHg	29~199 mmHg	29~134 mmHg
Diastolic		High limit	11~232 mmHg	11~150 mmHg	11~100 mmHg
		Low limit	10~231 mmHg	10~149 mmHg	10~99 mmHg
Mean		High limit	21~242 mmHg	21~165 mmHg	21~110 mmHg
		Low limit	20~241 mmHg	20~164 mmHg	20~109 mmHg
SpO_2		High limit	1~100%	1~100%	1~100%
		Low limit	0~99%	0~99%	0~99%
Pulse Rate		High limit	1~300bpm	1~350bpm	1~350bpm
		Low limit	0~299bpm	0~349bpm	0~349bpm
ST Segment		High Limit	-2.49Mv~+2.49mV	-2.49mV~+2.49mV	-2.49mV~+2.49mV
		Low Limit	-2.49mV~+2.49mV	-2.49mV~+2.49mV	-2.49mV~+2.49mV
Temperature Difference			0.0~5.0 ℃	0.0~5.0 ℃	0.0~5.0 ℃
Arterial Pressure	Systolic	High limit	（1~250）mmHg	(1~250)mmHg	(1~250)mmHg
		Low limit	（0~249）mmHg	(0~249)mmHg	(0~249)mmHg
	Diastolic	High limit	（1~250）mmHg	(1~250)mmHg	(1~250)mmHg
		Low limit	（0~249）mmHg	(0~249)mmHg	(0~249)mmHg
	Mean	High limit	（1~250）mmHg	(1~250)mmHg	(1~250)mmHg
		Low limit	（0~249）mmHg	(0~249)mmHg	(0~249)mmHg
Pulmonary Artery Pressure	Systolic	High limit	（1~120）mmHg	(1~120)mmHg	(1~120)mmHg
		Low limit	（0~119）mmHg	(0~119)mmHg	(0~119)mmHg
	Diastolic	High limit	（1~120）mmHg	(1~120)mmHg	(1~120)mmHg
		Low limit	（0~119）mmHg	(0~119)mmHg	(0~119)mmHg
	Mean	High limit	（1~120）mmHg	(1~120)mmHg	(1~120)mmHg
		Low limit	（0~119）mmHg	(0~119)mmHg	(0~119)mmHg
Central Venous Pressure	Systolic	High limit	（-9~40）mmHg	(-9~40)mmHg	(-9~40)mmHg
		Low limit	（-10~39）mmHg	(-10~39)mmHg	(-10~39)mmHg
	Diastolic	High limit	（-9~40）mmHg	(-9~40)mmHg	(-9~40)mmHg
		Low limit	（-10~39）mmHg	(-10~39)mmHg	(-10~39)mmHg
	Mean	High limit	（-9~40）mmHg	(-9~40)mmHg	(-9~40)mmHg
		Low limit	（-10~39）mmHg	(-10~39)mmHg	(-10~39)mmHg
CO_2	Respiration Rate	High limit	（1~120）rpm	(1~150)rpm	(1~150)rpm
		Low limit	（0~119）rpm	(0~149)rpm	(0~149)rpm
	$EtCO_2$	High limit	（1~100）mmHg	(1~100) mmHg	(1~100) mmHg
		Low limit	（0~99）mmHg	(0~99) mmHg	(0~99) mmHg
	$InsCO_2$	High limit	（1~30）mmHg	(1~30) mmHg	(1~30) mmHg
		Low limit	（0~29）mmHg	(0~29) mmHg	(0~29) mmHg

12.3 Abbreviation of Arrhythmia

1. ECG TACHY
2. ECG BRADY
3. ECG VPCEST
4. MISS BEAT
5. VE EARLY
6. SVE EARLY
7. VE COUPLET
8. SVE COUPLET
9. VE RUN
10. SVE RUN
11. VE SHORT RUN
12. SVE SHORT RUN
13. VE BIGEMINY
14. SVE BIGEMINY
15. VE TRIGEMINY
16. SVE TRIGEMINY
17. VE INSERT
18. SVE INSERT
19. VE RONT
20. SVE RONT

12.4 Status/Error during NIBP Monitoring

“Cuff error” —cuff is not wrapped correctly, or is not connected

“Air leak” —Air moving part, tube or the cuff leak air.

“Pressure error” —Unstable cuff pressure or tangled cuff tubing

“Signal weak” —Very weak signal because of the cuff, or the patient has very weak pulse

“Over extent” —The measurement range exceeds 255 mmHg (Infant patient over 135 mmHg)

“Over motion” —The repeated measurement due to moving, excessive noise during the stepping inflation and measuring pressure and pulse, e.g. during patient shaking motion

“Signal overflow” —Blood pressure amplifier overflow due to excessive movement

“Leak in gas run” —Leaking during the pneumatic device testing

“System error” —Abnormal condition of CPU, such as register overflow, divided by zero

“Adult” —The blood pressure measuring now is in adult mode. In this case, it is not allowed to monitoring pediatric or neonatal patient. Otherwise, there may be serious danger to the infant monitored.

“Infant” —The blood pressure module is now worked in infant measuring mode.

“PROBE OFF” —SpO_2 probe fell off

“LEADS OFF” —The ECG electrodes or cable fell off

“LEARNING” —Learning arrhythmia for 15 seconds

“DEMO” —The monitor is displaying the demo waveforms, which are generated by the monitor itself.

12.5 Status/Error during CO_2 Monitoring

Suggested Message/Response	Description
"Sensor Over Temp" Make sure sensor is not exposed to extreme heat (heat lamp, etc.). If error persists, return sensor to factory for servicing.	The sensor temperature is greater than 40 °C.
"Sensor Faulty" Check that the sensor is properly plugged in. Reinsert or reset the sensor if necessary. If error persists, return sensor to factory for servicing	One of the following conditions exist: Source Current Failure, EEPROM Checksum Faulty, Hardware Error
No Parameter Message The host must set the Barometric Pressure and compensations to clear this error; no user intervention should be required.	Barometric Pressure and/or gas compensations have not been set since power on. For CO_2 to be calculated with the stated accuracy, these values should be set whenever the sensor is plugged in.
"Module in Sleep Mode"	This bit is set when sensor has been placed in sleep mode.
"Zero In Progress "	A Module Zero is currently in progress.
"Sensor Warm Up" This error condition is normal at startup. This error should clear when the warm up is complete.	One of the following conditions exist: Sensor under temperature Temperature not stable Source Current unstable
"Check Sampling Line" Check that the sampling line is not occluded or kinked.	This error occurs whenever the pneumatic pressure is outside the expected range.
"Zero Required" To clear, check airway adapter and clean if necessary. If this does not correct the error, perform an adapter zero. If you must adapter zero more than once, a possible hardware error may exist.	One of the following conditions exist: Zero Required; Zero Required: Zero Error
"CO_2 Out of Range" If error persists, perform a zero.	The value being calculated is greater than the upper CO_2 limit (150 mmHg, 20.0 kPa, or 19.7 %). The maximum value output is the upper CO_2 limit.
"Check Airway Adapter" To clear, clean airway adapter if mucus or moisture is seen. If the adapter is clean, perform a Capnostat zero.	Usually caused when the airway adapter is removed from the sensor or when there is an optical blockage on the windows of the airway adapter. May also be caused by failure to perform sensor zero to when adapter type is changed.
The Sensor not Ready	This is prompted if the CO_2 sensor is not ready for a Capnostat Zero. If the "Zero Required" and this massage both prompt message both promptone or more of the following conditions may exist: • Breaths detected • Temperature is not stable • Source Current unstable • In sleep mode.
Zero in already progress	Normal zero calibration is in already progress.
Zero Fault and Breaths Detected	Zero attempted and breaths have been detected in the last 20 seconds.
Zero Ok	Zero calibration is successful

12.6 Typical Pressures and CO_2 Readings at Altitudes

Altitude	Barometric Pressure(mmHg)	$EtCO_2$ Reading	
		（%）	（mmHg）
0m	760	5	38.0
70m	754	5	37.7
100m	751	5	37.5
200m	743	5	37.1
1500m	641	5	32.0
3000m	537	5	26.8
5000m	420	5	21.0

12.7 Accessories List

Part No.	Part Name	Remark
15010513	ECG cable	
5101-0101310	ECG electrode	
15044051	Adult SpO_2 Finger clip Sensor	
15044061	Adult SpO_2 Finger rubber Sensor	
15044041	Pediatric SpO_2 Finger clip Sensor	
15024402	Adult NIBP cuff(25~35cm)	
15021402	Small-sized Pediatric NIBP Cuff	
15022402	Middle-sized Pediatric NIBP Cuff	
15023402	Large-sized Pediatric NIBP	
2903-0000000	Power cord	
900093	Net wire	

For more information regarding the accessories, please contact your local sales representative or the manufacturer.

Note: Part no. is subject to change without prior notice, please refer to the label of parts or packlist.

12.8 Instructions for SpO_2 Probe

Instructions for Pediatric SpO_2 Finger Clip Sensor

Intended Use

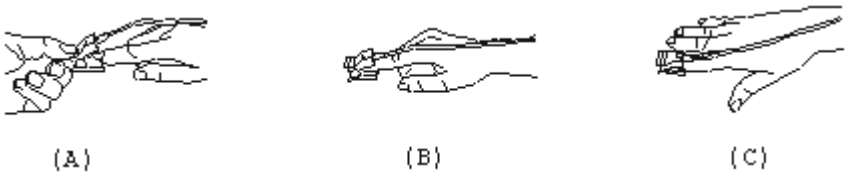
When used with a compatible patient monitor or a pulse oximeter device, the sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for pediatric patients weighing between 10~40kg.

Contraindications

This sensor is contraindicated for use on active patients or for prolonged use.

Instructions for Use

1) With the upper and lower jaws open, place an index finger evenly on the base of the clip. Push the finger tip against the stop so that it is over the sensor window (A). If an index finger cannot be positioned correctly, or is not available, other fingers can be used.
2) Note: When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff, or intravascular infusion line.
3) Spread open the rear tabs of the sensor to provide even force over the length of the pads (B).
4) The sensor should be oriented in such a way that the cable is positioned along the top of the hand (C).
5) Plug the sensor into the oximeter and verify proper operation as described in the user manual.



6) Inspect the monitoring site every 1~2 hours for skin integrity.
7) Before each use, surface-clean sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution.

Caution: Do not sterilize by irradiation steam, or ethylene oxide.

Warnings

1) Some factors may affect the accuracy of saturation measurements. Such factors include: excessive patient motion, fingernail polish, use of intravascular dyes, excessive light, poor blood perfusion in the finger, extreme finger sizes or improper placement of the sensor.
2) Using the sensor in the presence of bright lights may result in inaccurate measurements. In such cases, cover the sensor site with an opaque material.
3) The sensor must be moved to a new site at least every 3 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.
4) Do not apply tape to secure the sensor in place or to tape it shut; venous pulsation may lead to inaccurate saturation measurements.
5) Do not immerse sensor as it causes short.
6) Do not use NIBP or other constructing instruments on same appendage as sensor for blood flow interrupted by NIBP cuff or circulatory patient condition will result in no pulse found or loss of pulse.
7) Do not use the sensor or other oximetry sensors during MRI scanning.
8) Carefully route cables to reduce the possibility of patient entanglement or strangulation.
9) Do not alter or modify the sensor. Alterations or modifications may affect performance or accuracy.
10) Do not use the sensor if the sensor or the sensor cable appears damaged.

Instructions for Adult SpO_2 Finger Rubber Sensor

Intended Use

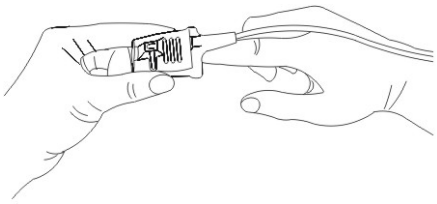
When used with a compatible patient monitor or a pulse oximeter device, this SpO_2 sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for patients weighing greater than 50kg.

Contraindications

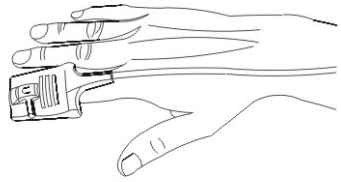
This sensor is contraindicated for use on active patients or for prolonged use.

Instructions for Use

1) Hold the sensor with its opening towards the patient's index finger (A). The sensor should be oriented in such a way that the sensor side with a finger tip sign is positioned on the top.
2) Insert the patient's index finger into the sensor until the fingernail tip rests against the stop at the end of the sensor. Adjust the finger to be placed evenly on the middle base of the sensor. Direct the cable along the top of the patient's hand. Apply adhesive tape to secure the cable (B). If an index finger cannot be positioned correctly, or is not available, other fingers can be used.
3) Plug the sensor into the oximeter and verify proper operation as described in the user manual.



(A)



(B)

4) Inspect the monitoring site every 1~2 hours for skin integrity.

Cleaning & Disinfection

Unplug the sensor before cleaning or disinfecting. Surface-clean sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution.

Caution: Do not sterilize by irradiation steam, or ethylene oxide.

Warnings

1) This sensor is for use only with compatible patient monitors or pulse oximeter devices. Use of this sensor with instruments other than compatibles may result in improper performance.
2) Some factors may affect the accuracy of saturation measurements. Such factors include: excessive patient motion, fingernail polish, use of intravascular dyes, excessive light, poorly perfused finger, extreme finger sizes or improper placement of the sensor.
3) The sensor site must be checked for skin integrity at least every 1~2 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor to another finger.
4) Do not use NIBP or other constructing instruments on same appendage as sensor for blood flow interrupted by NIBP cuff or circulatory patient condition will result in no pulse found or loss of pulse. Do not use the sensor during MRI scanning.
5) Carefully route cables to reduce the possibility of patient entanglement or strangulation.
6) Do not alter or modify the sensor. Alterations or modifications may affect performance or accuracy.
7) Do not use the sensor if the sensor or the sensor cable appears damaged.

Instructions for Adult SpO_2 Finger Clip Sensor

Intended Use

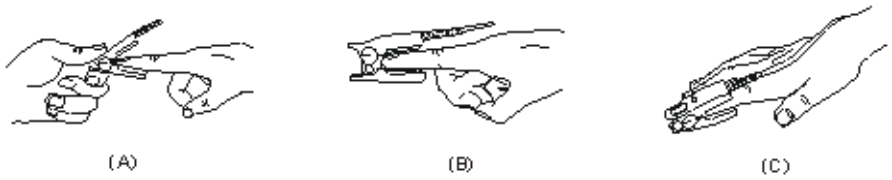
When used with a compatible patient monitor or a pulse oximeter device, the sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO_2) and pulse rate monitoring for patients weighing greater than 40kg.

Contraindications

This sensor is contraindicated for use on active patients or for prolonged use.

Instructions for Use

1) With the upper and lower jaws open, place an index finger evenly on the base of the clip. Push the finger tip against the stop so that it is over the sensor window (A). If an index finger cannot be positioned correctly, or is not available, other fingers can be used.
2) Note: When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff, or intravascular infusion line.
3) Spread open the rear tabs of the sensor to provide even force over the length of the pads (B).
4) The sensor should be oriented in such a way that the cable is positioned along the top of the hand (C).



5) Plug the sensor into the oximeter and verify proper operation as described in the user manual.
6) Inspect the monitoring site every 1~2 hours for skin integrity.
7) Before each use, surface-clean sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution.

Caution: Do not sterilize by irradiation steam, or ethylene oxide.

Warnings

1) Some factors may affect the accuracy of saturation measurements. Such factors include: excessive patient motion, fingernail polish, use of intravascular dyes, excessive light, poorly perfused finger, extreme finger sizes or improper placement of the sensor.
2) Using the sensor in the presence of bright lights may result in inaccurate measurements. In such cases, cover the sensor site with an opaque material.
3) The sensor must be moved to a new site at least every 3 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.
4) Do not apply tape to secure the sensor in place or to tape it shut; venous pulsation may lead to inaccurate saturation measurements.
5) Do not immerse sensor as it causes short.
6) Do not use NIBP or other constructing instruments on same appendage as sensor for blood flow interrupted by NIBP cuff or circulatory patient condition will result in no pulse found or loss of pulse.
7) Do not use the sensor or other oximetry sensors during MRI scanning.
8) Carefully route cables to reduce the possibility of patient entanglement or strangulation.
9) Do not alter or modify the sensor. Alterations or modifications may affect performance or accuracy.
10) Do not use the sensor if the sensor or the sensor cable appears damaged.

Creative offers a 6-momth warranty against manufacturing defects for the SpO_2 sensors mentioned above in its undamaged condition.

If you have any question regarding any of SpO_2 sensor instructions, please contact market @ creative-sz.com your local dealer.

Delton

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